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Nguyen et al.

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- (54) **MULTIPLE BIAS SURGICAL FASTENER**
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- (73) Assignee: **Medtronic, Inc.**, Minneapolis, MN (US)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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Related U.S. Application Data

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- (51) **Int. Cl.**
B21F 1/00 (2006.01)
- (52) **U.S. Cl.** **29/447**; 267/168; 606/78; 606/157; 606/219; 606/221
- (58) **Field of Classification Search** 606/151, 606/157, 158, 219, 220, 221, 78, 200; 24/67.3, 24/67.5; 128/830, 831; 267/166, 168, 177; 623/1.18; 29/34 D, 896.8, 402.21, 447
See application file for complete search history.

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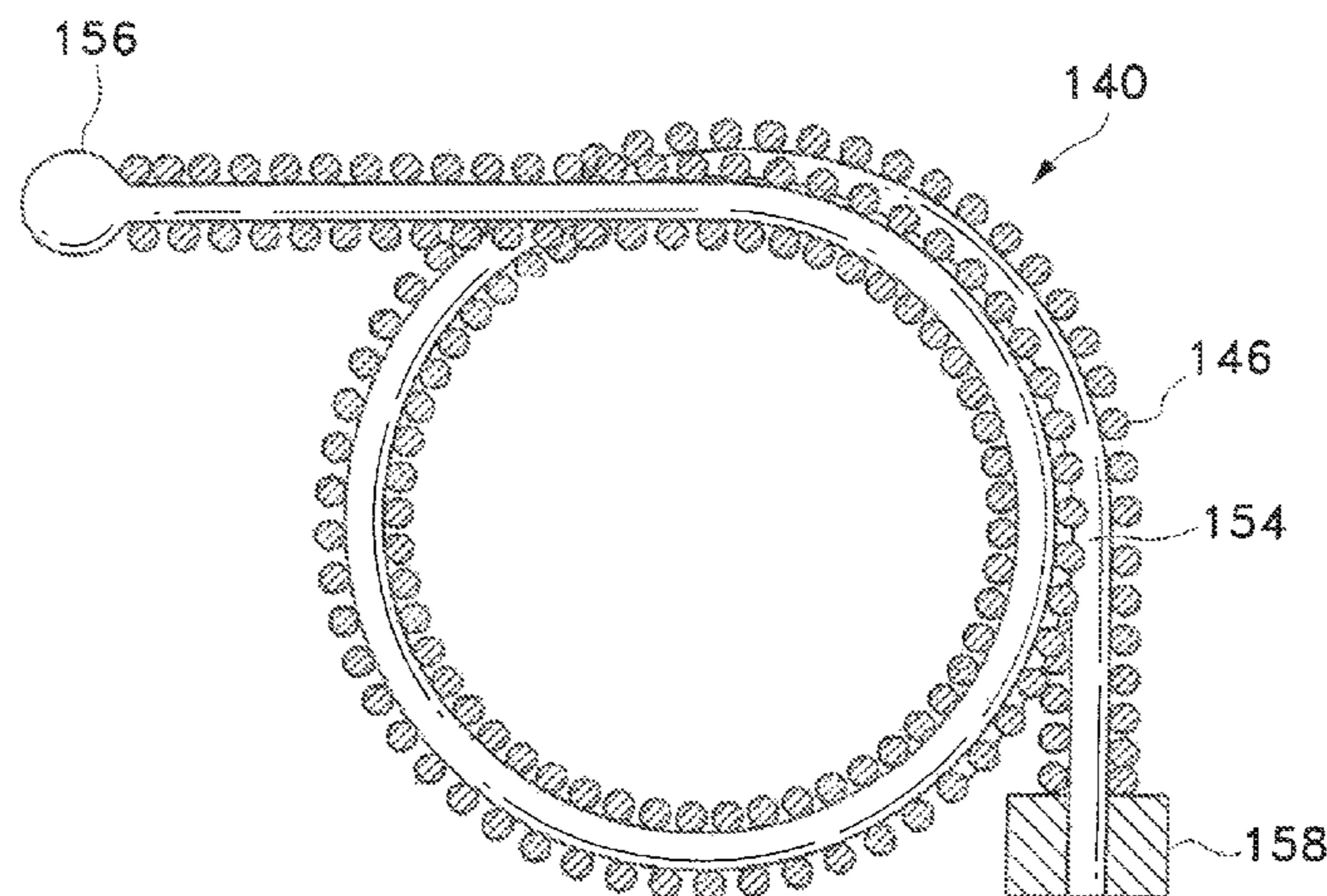
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- (57) **ABSTRACT**

A surgical fastener comprising a clip movable between an open configuration and a closed configuration and a biasing member contacting the clip and biasing the dip to its open configuration when the biasing member is actuated. The biasing member and clip both tend to assume the closed configuration when no external forces are applied to them. A needle may be releasably attached to the clip. Methods for making the fasteners are also disclosed, in which both the clip and the biasing member are set in the closed position.

17 Claims, 21 Drawing Sheets



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International Preliminary Examination Report PCT/US98/00462.

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Written Opinion PCT/US99/12563.

Written Opinion PCT/US99/12566.

Written Opinion PCT/US00/09092.

Written Opinion PCT/US01/10501.

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International Preliminary Report on Patentability PCT/US2004/023728.

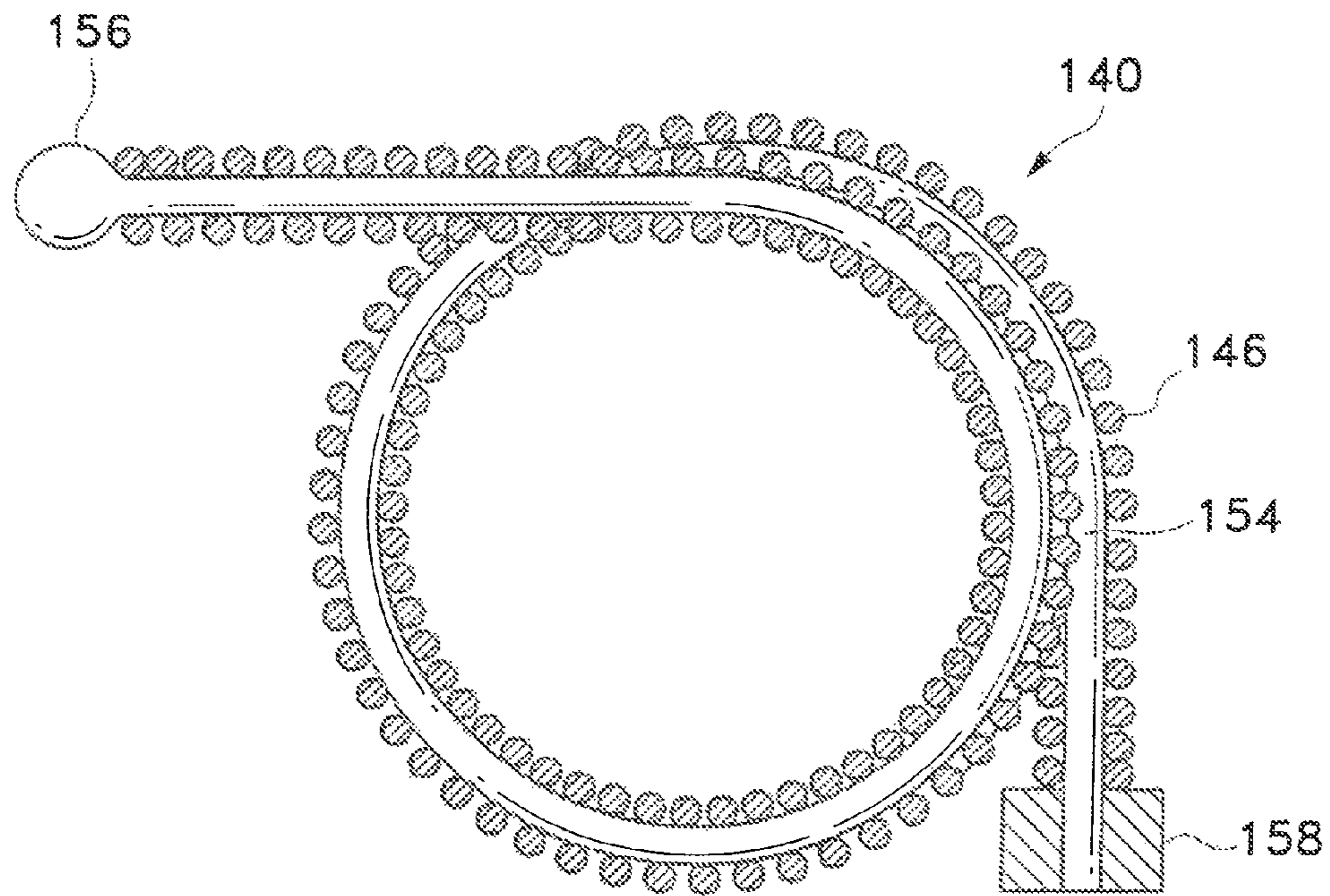


FIG. 1A

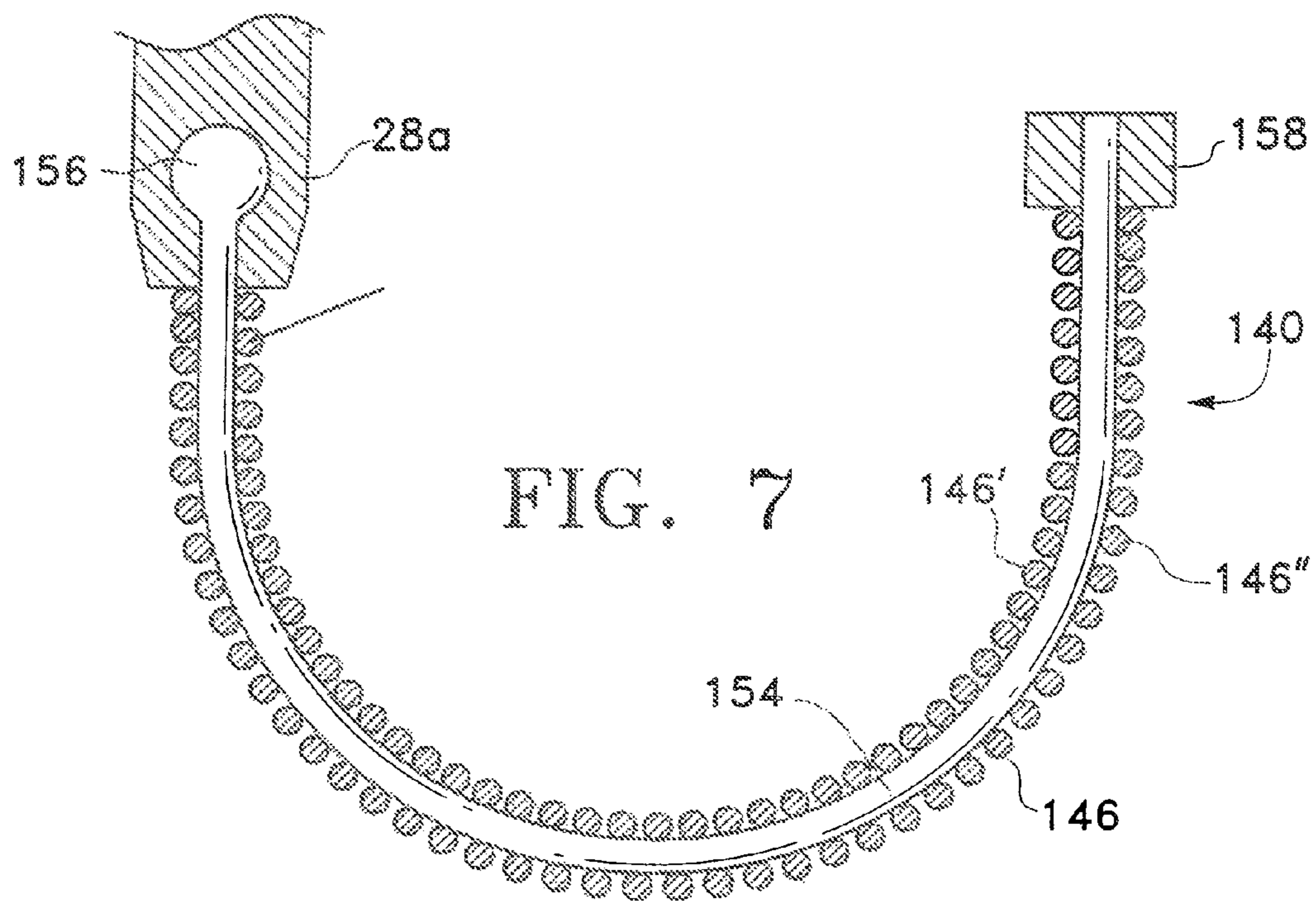
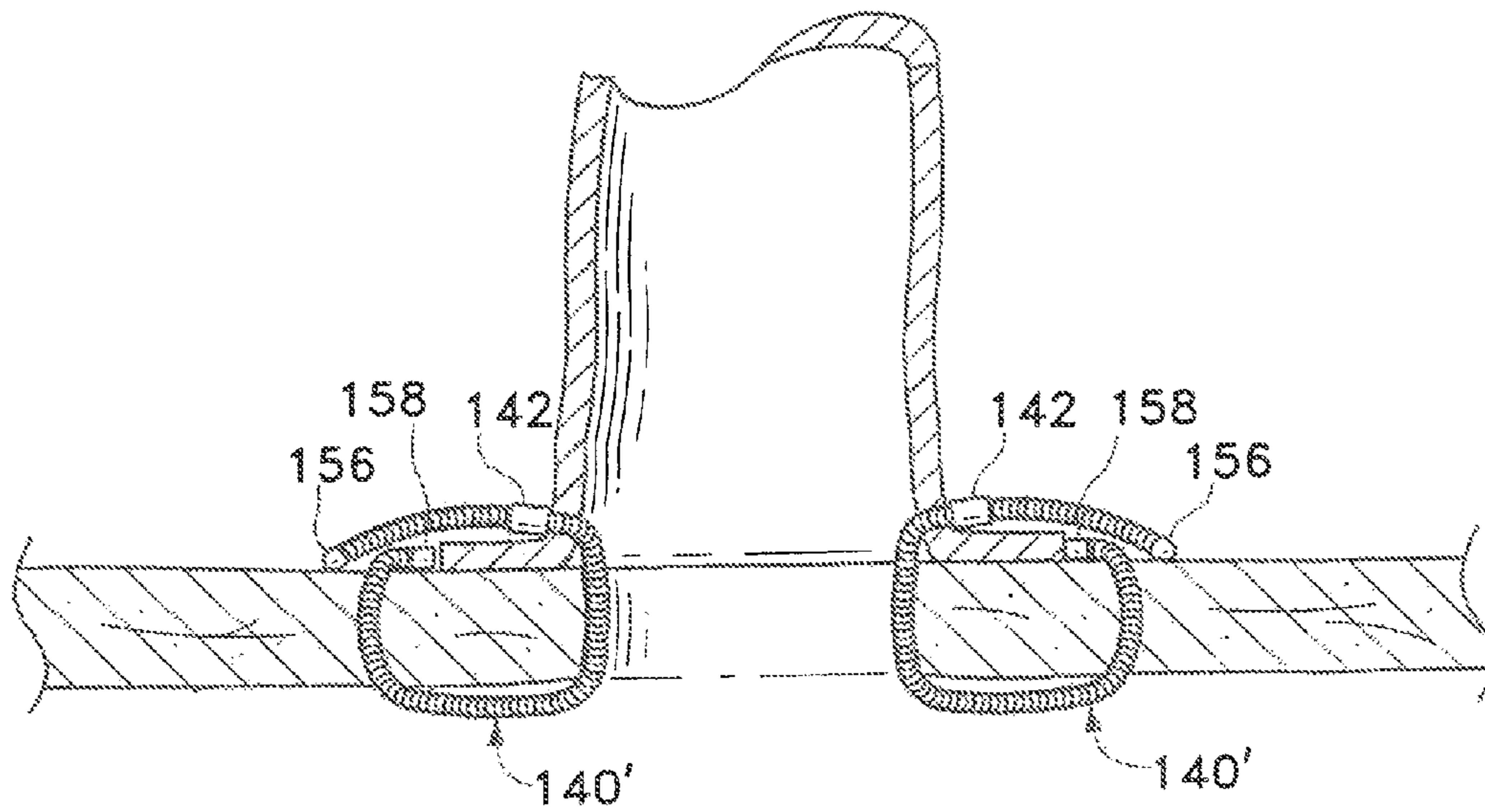
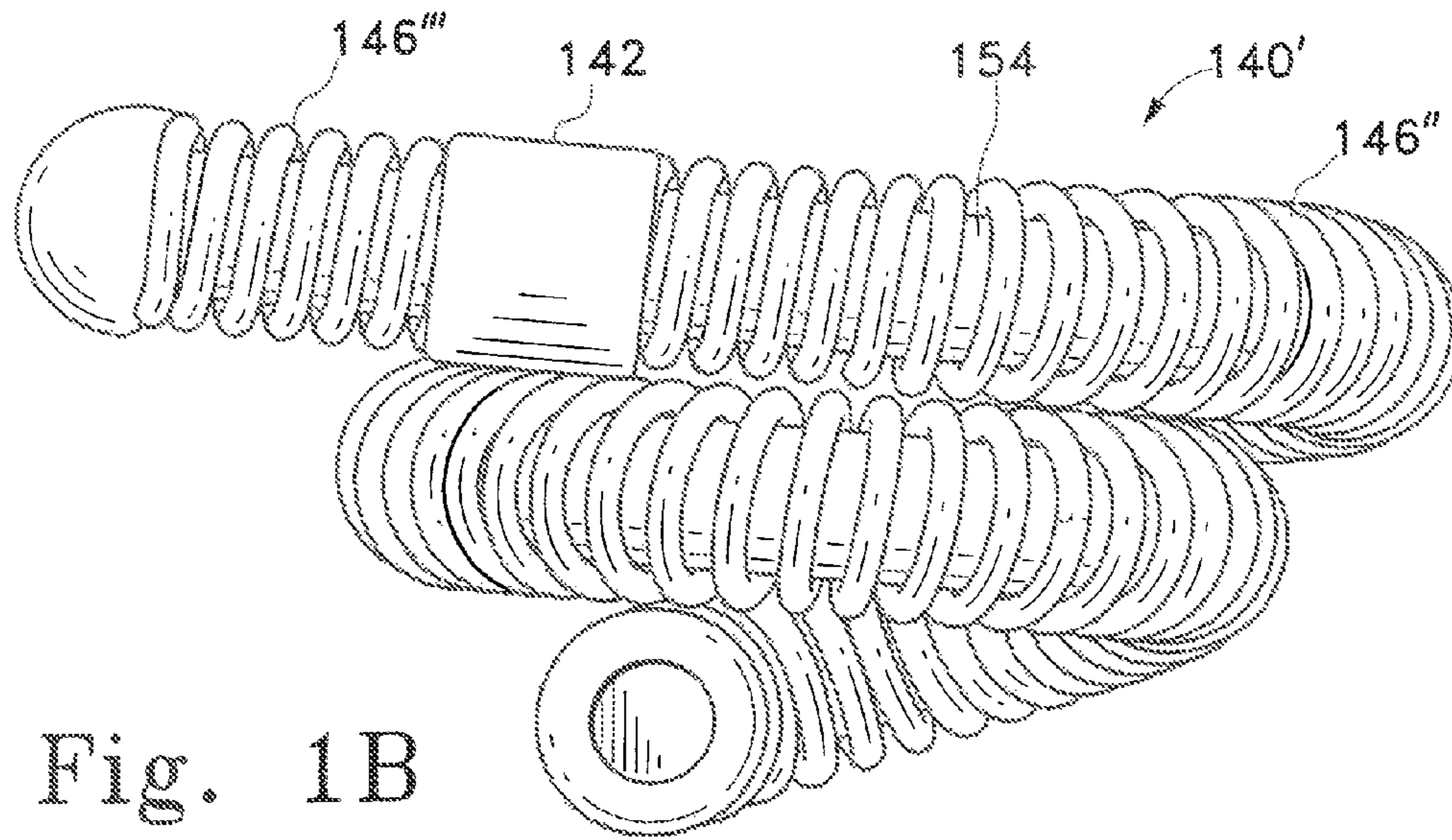


FIG. 7



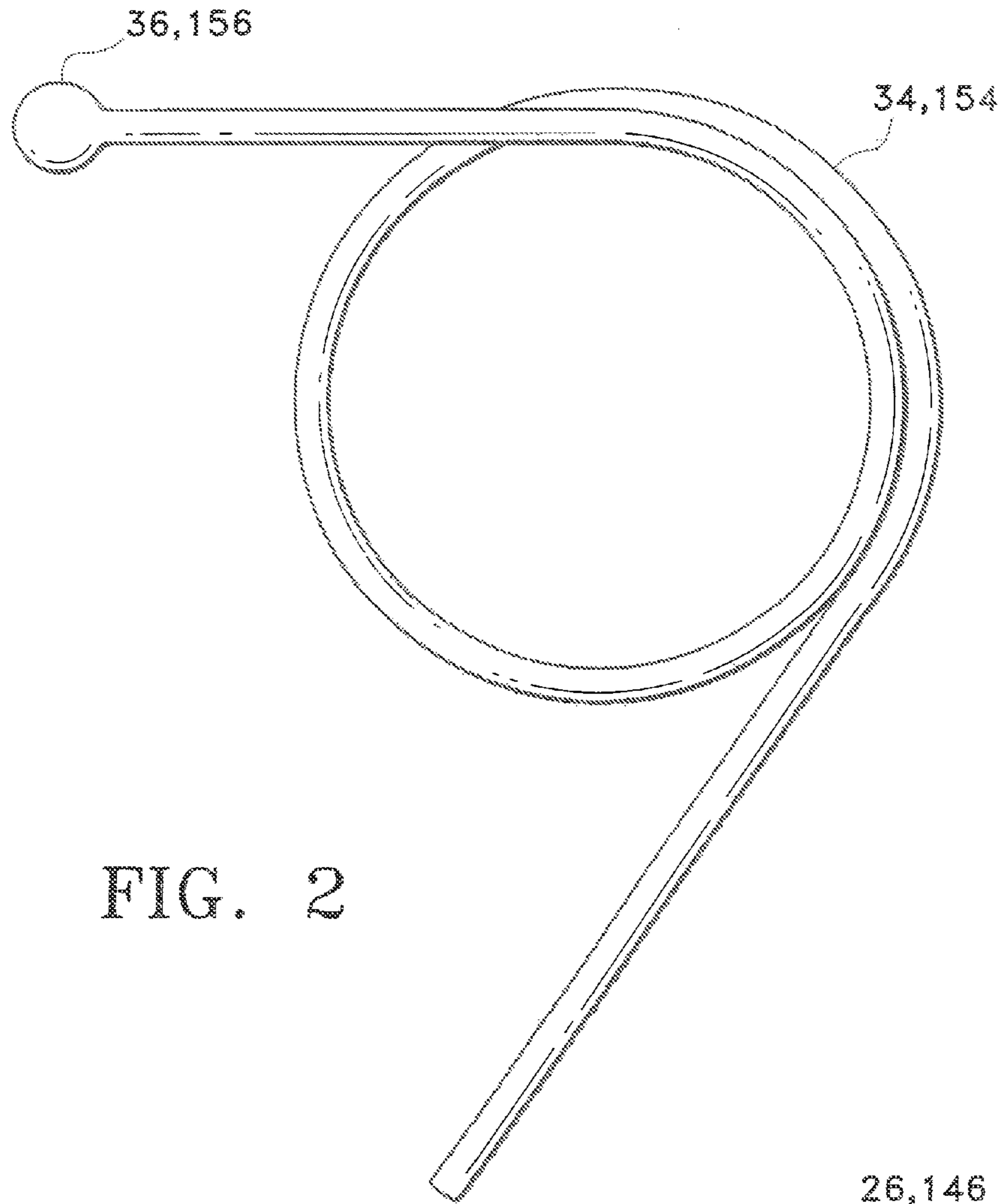


FIG. 2

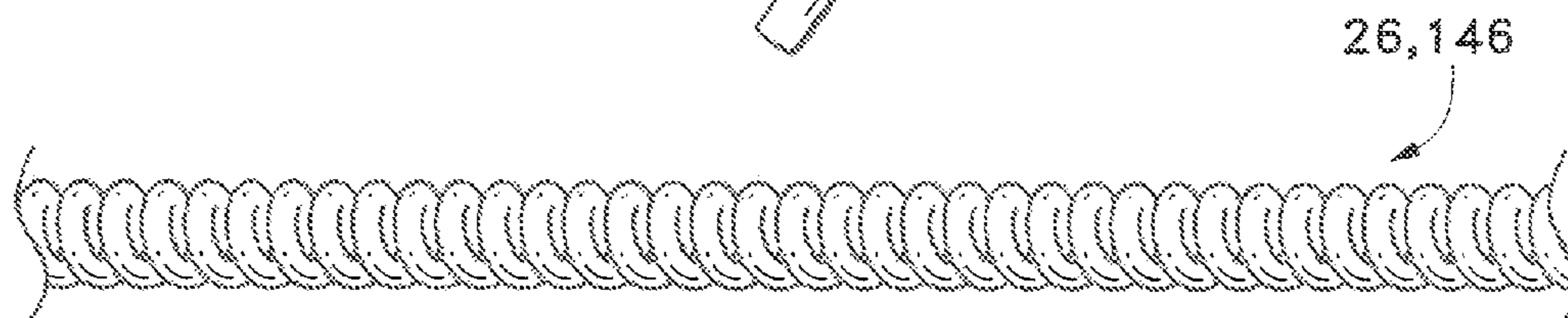


FIG. 3A

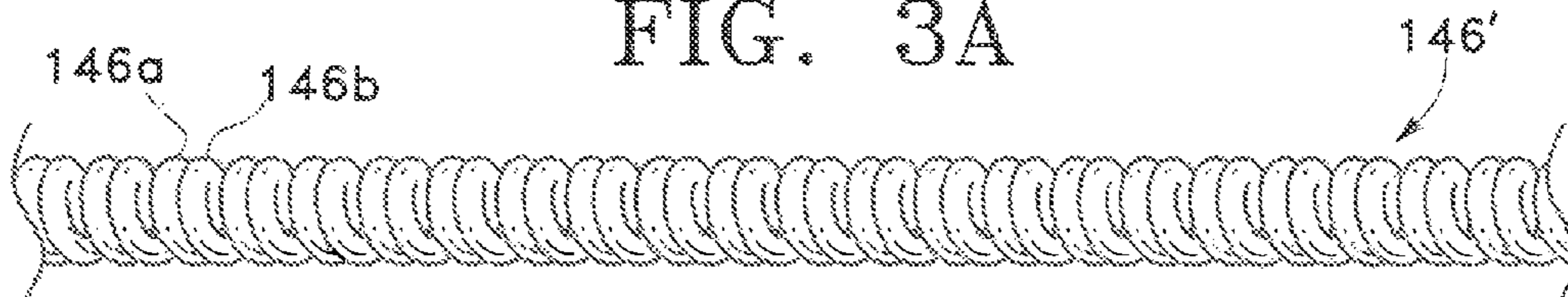


FIG. 3B

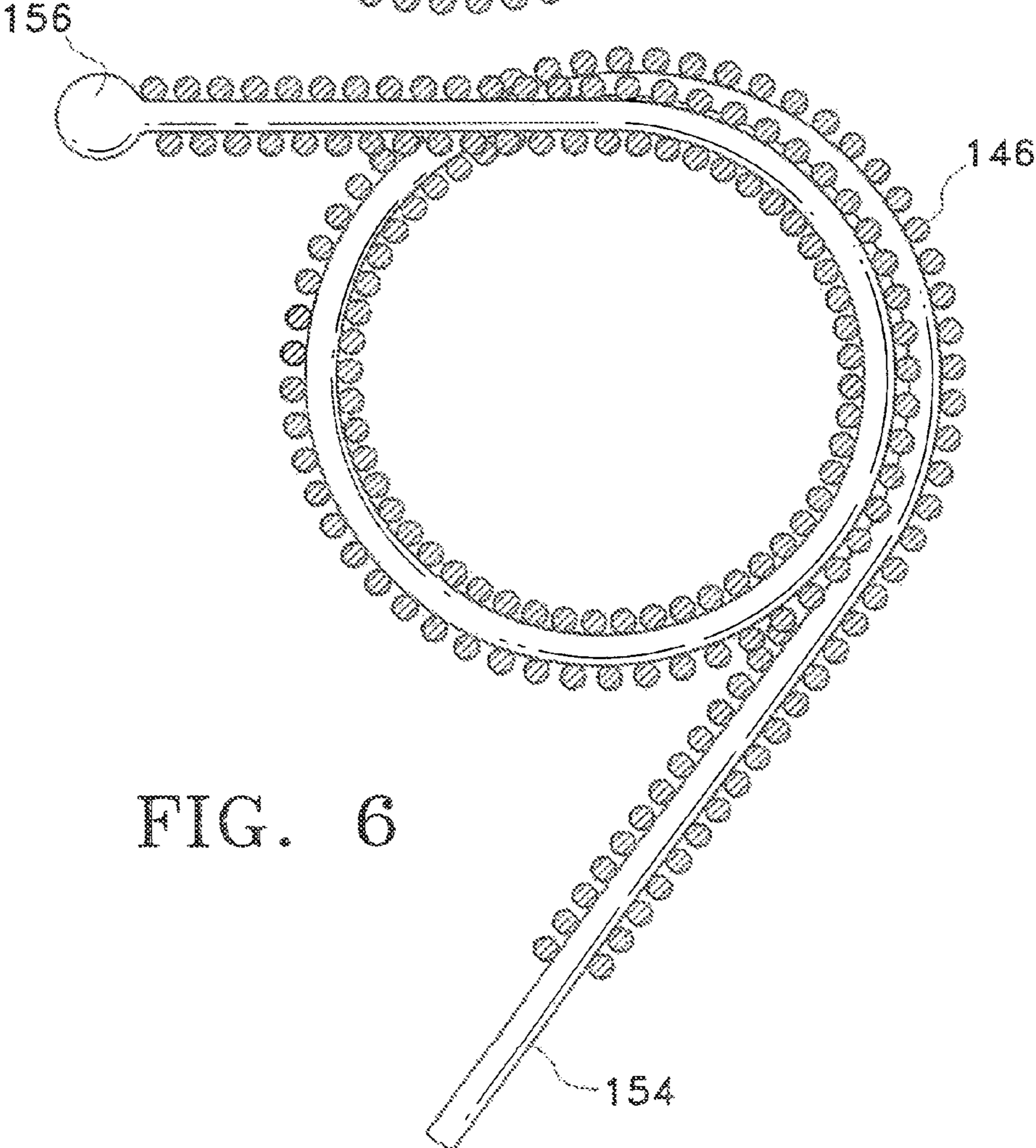
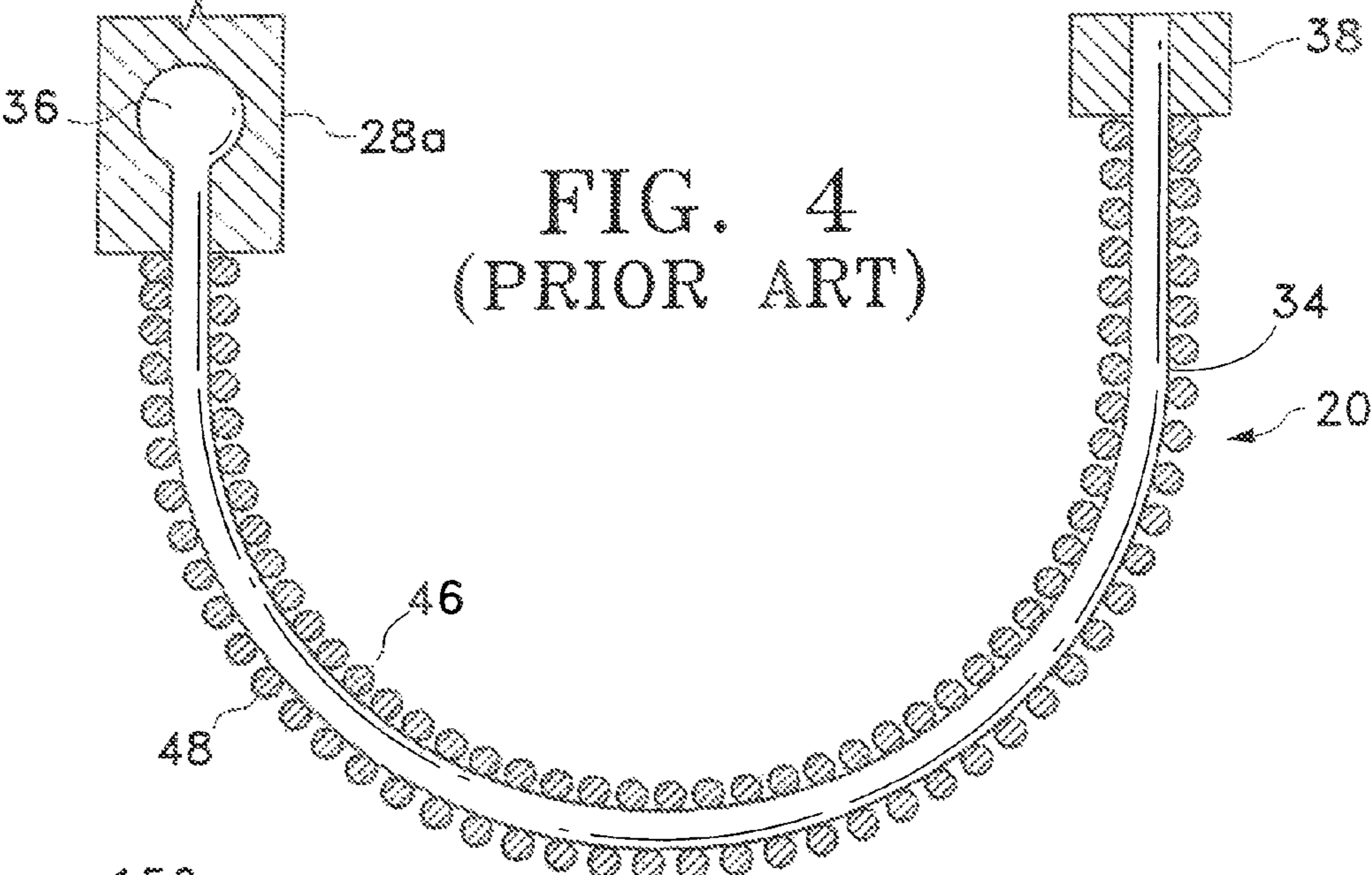


FIG. 6

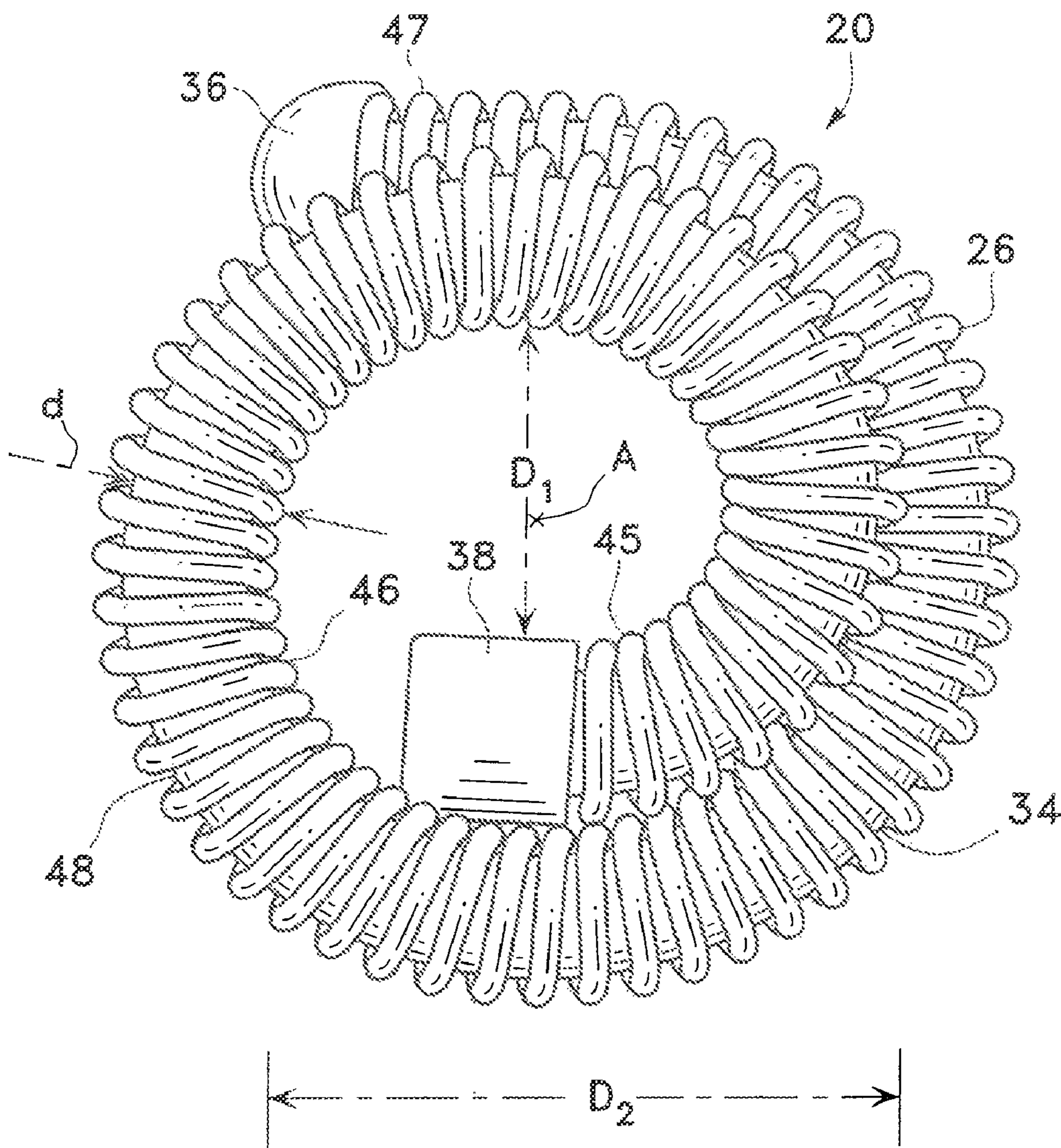


FIG. 5
(PRIOR ART)

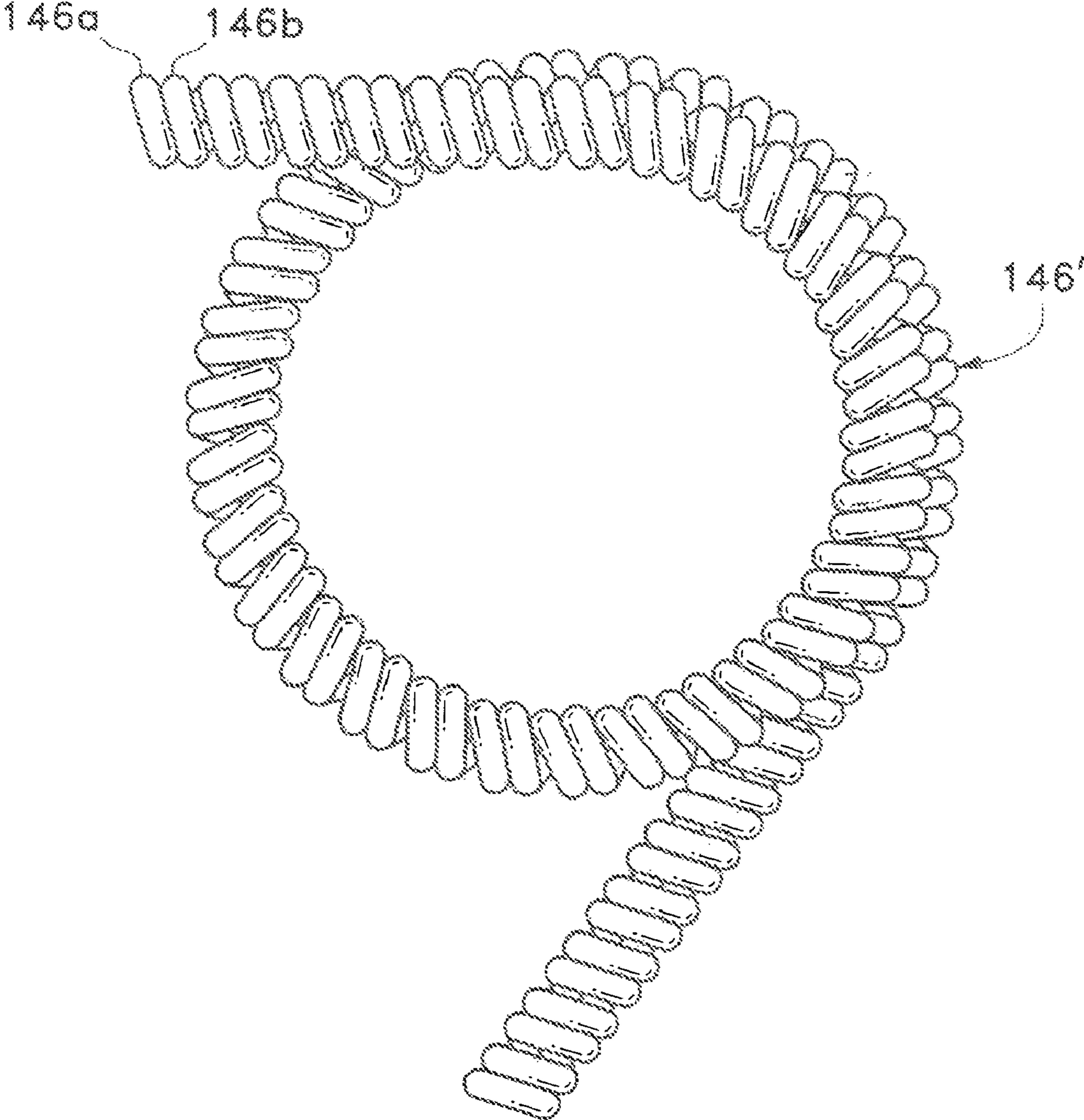


FIG. 8

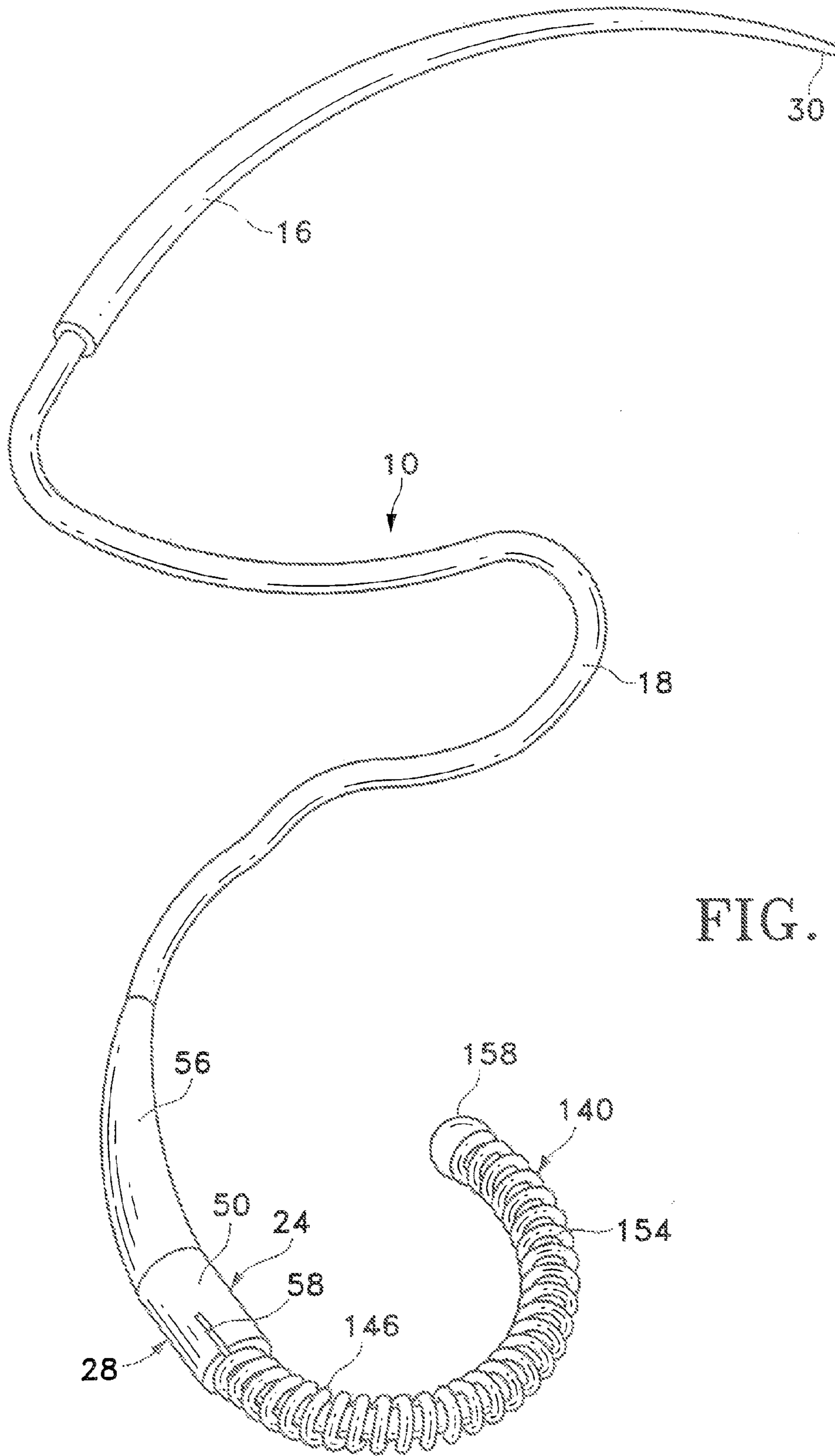


FIG. 9

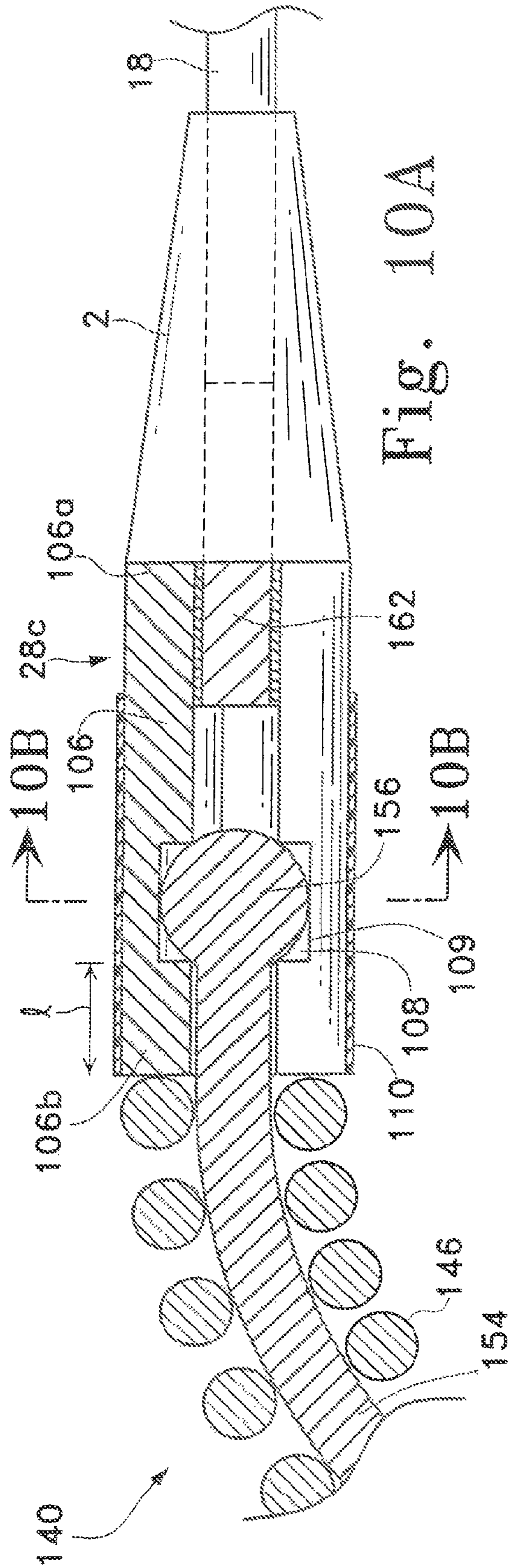


Fig. 10A

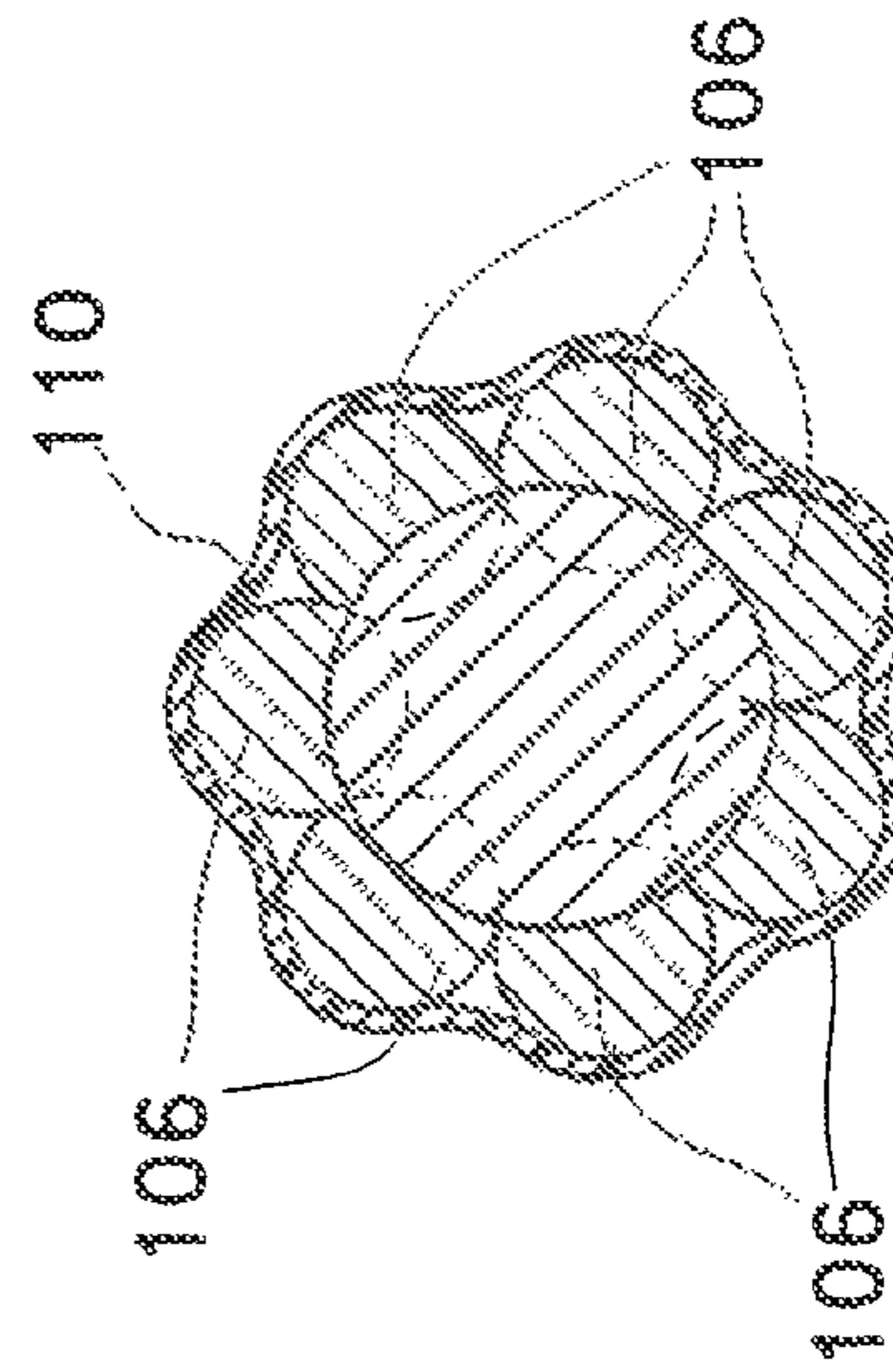


Fig. 10B

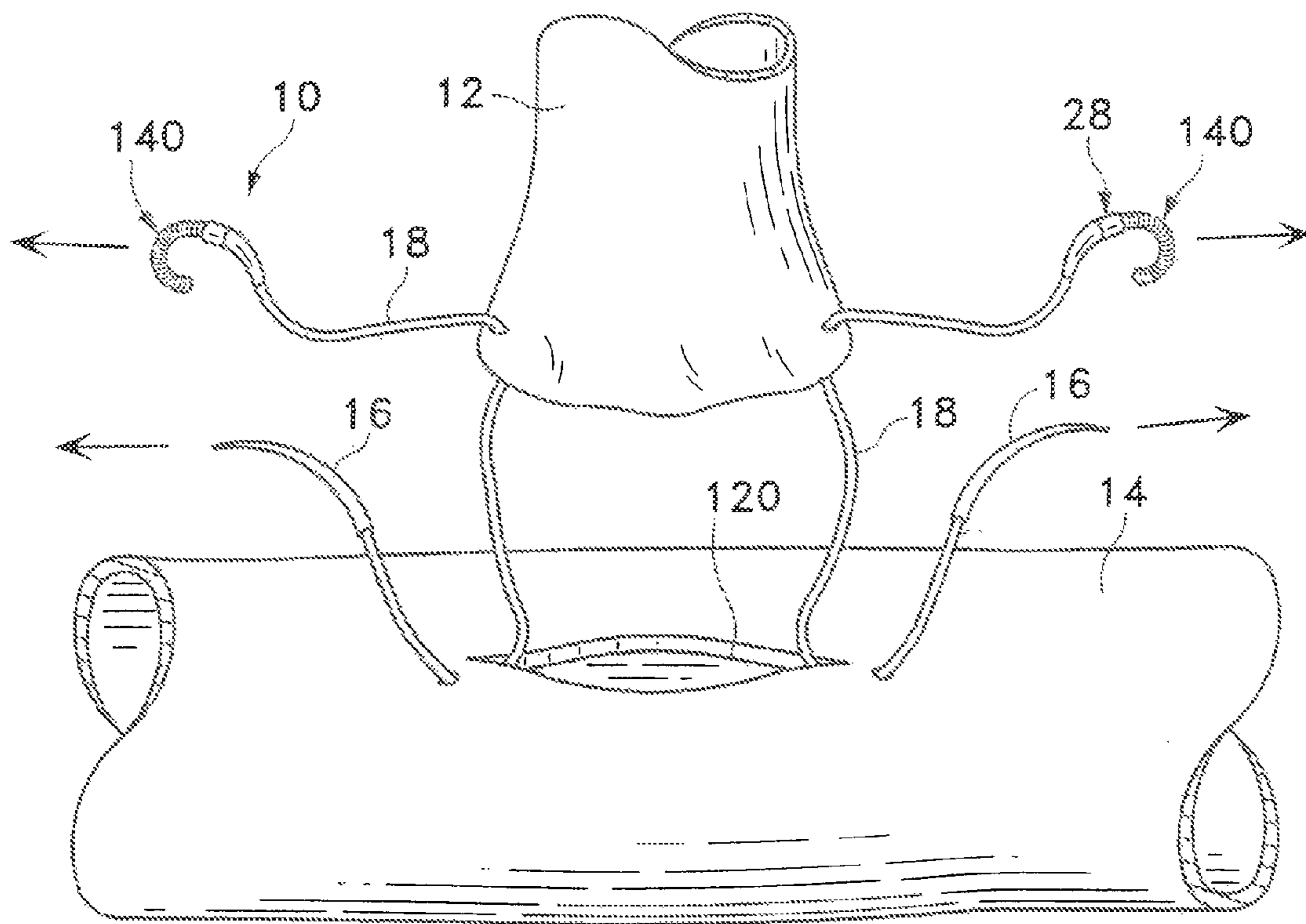


FIG. 11A

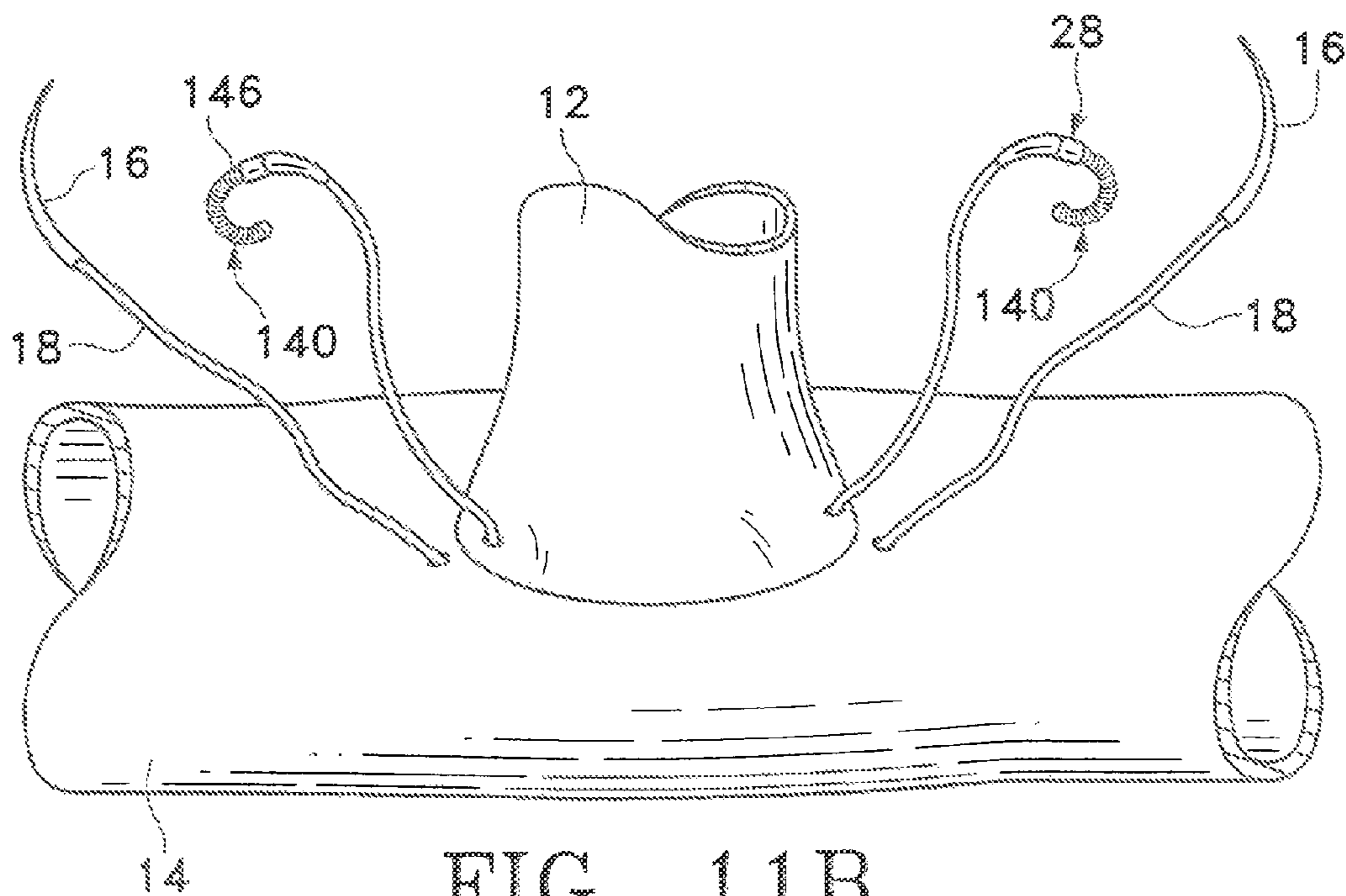


FIG. 11B

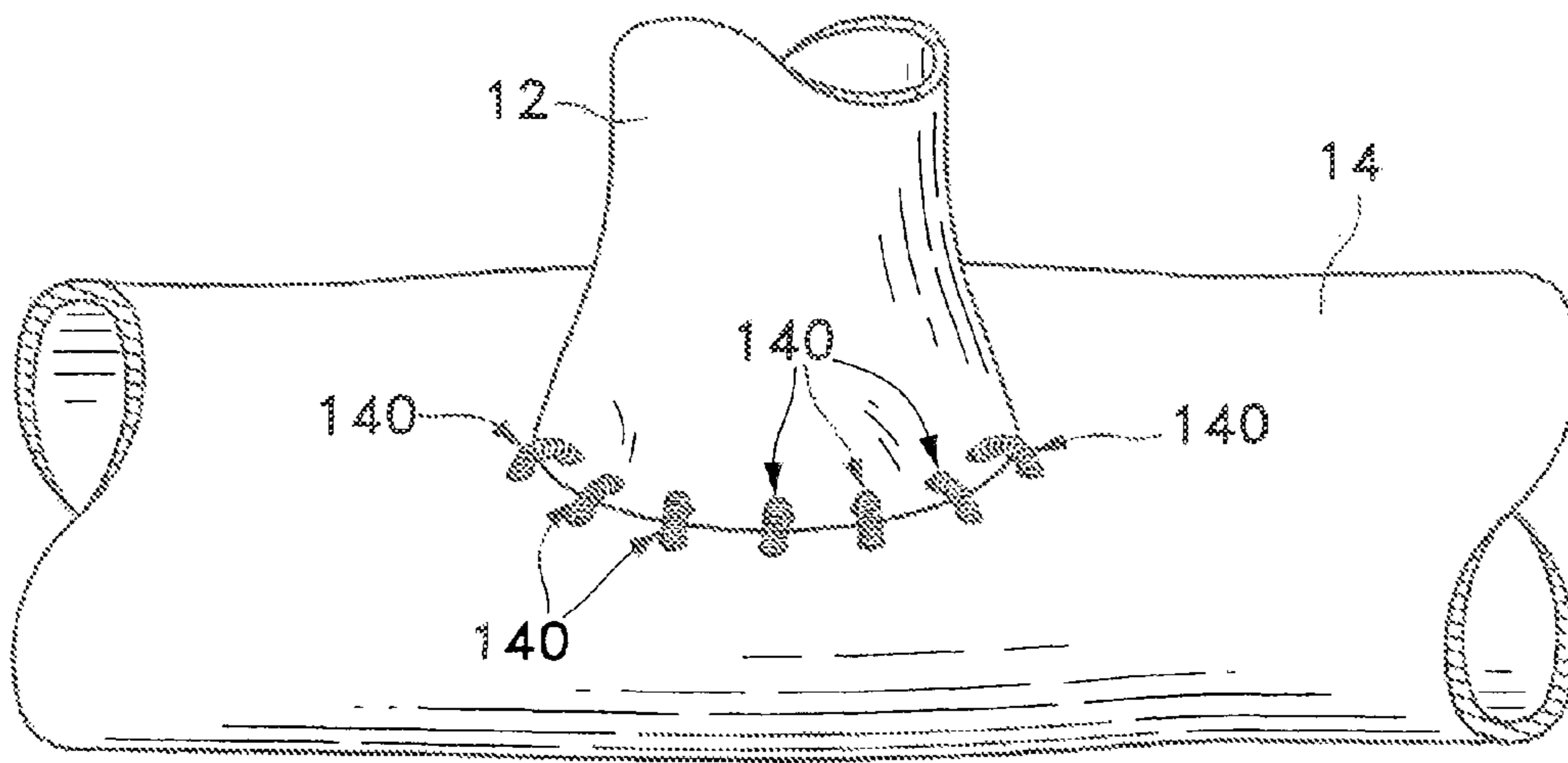


FIG. 11C

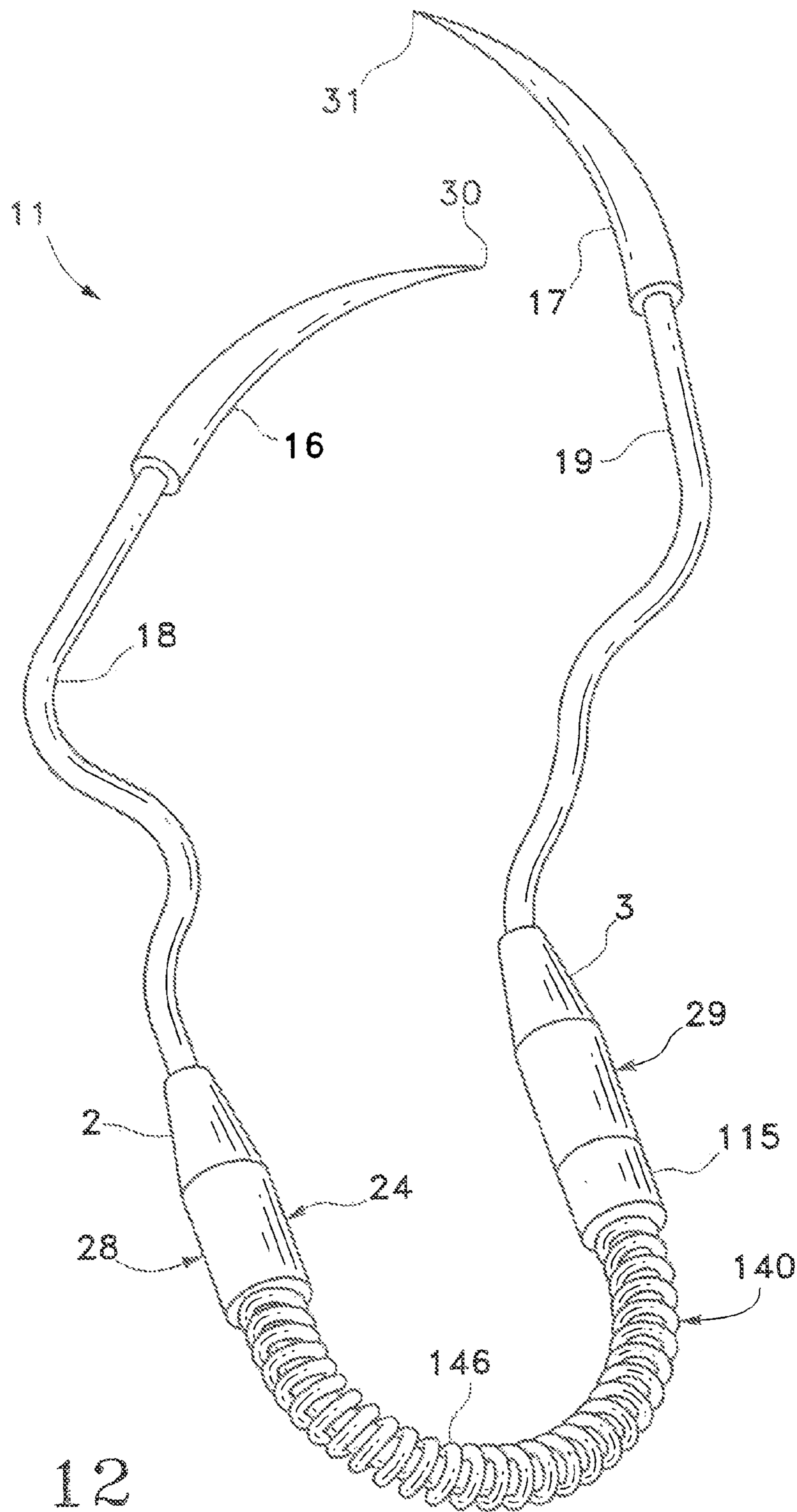


FIG. 12

FIG. 13A

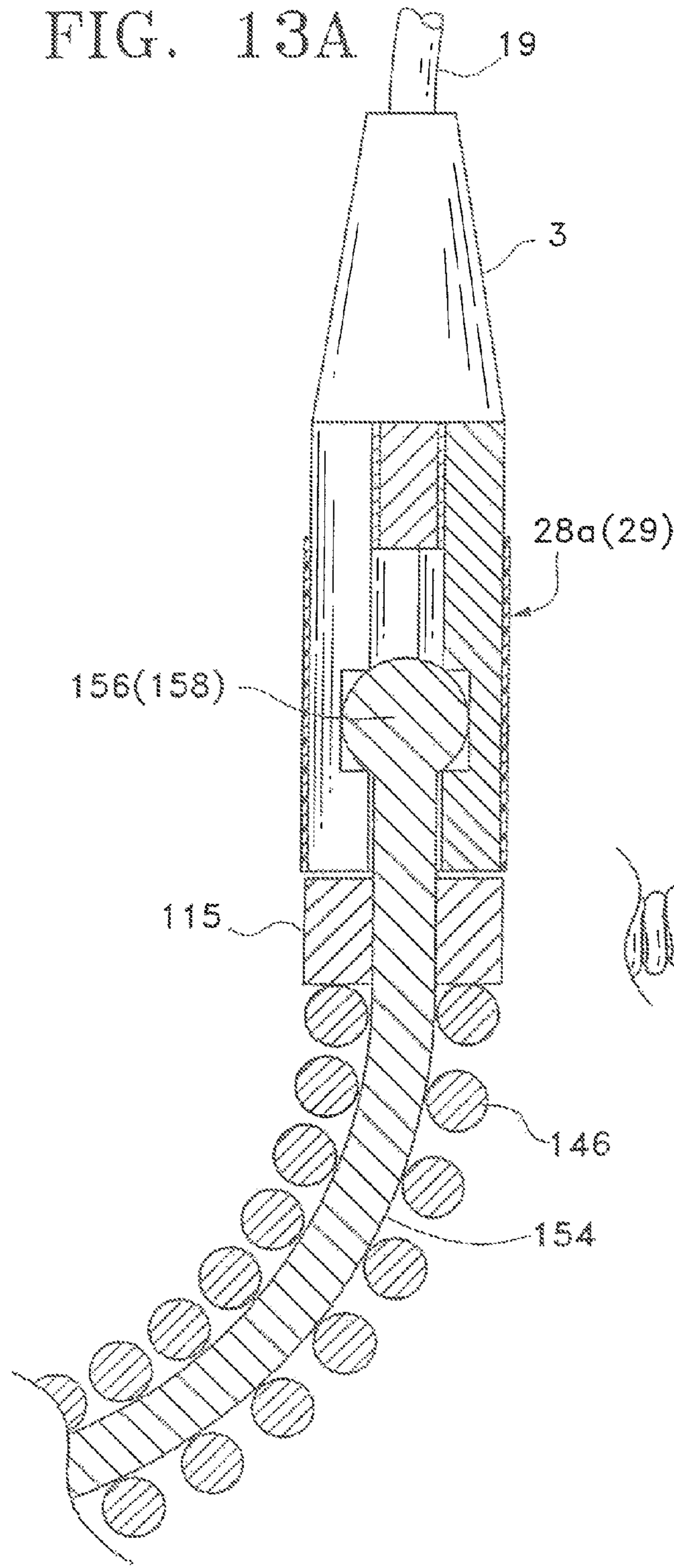


FIG. 13B

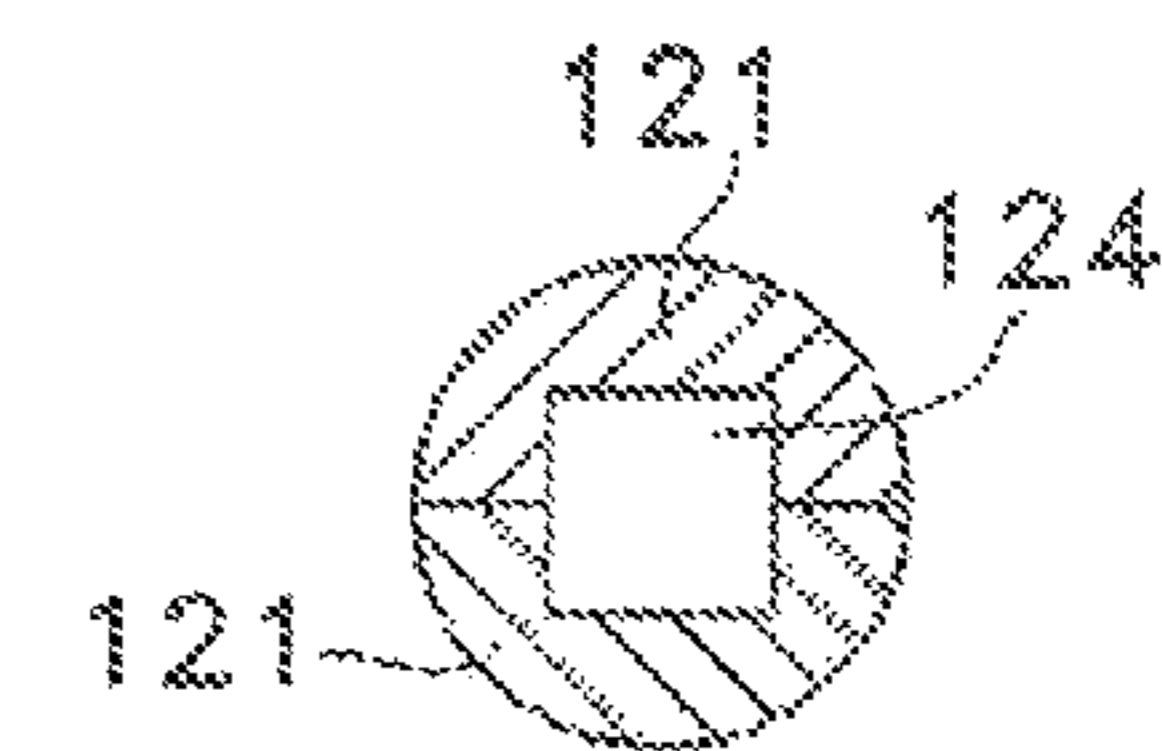
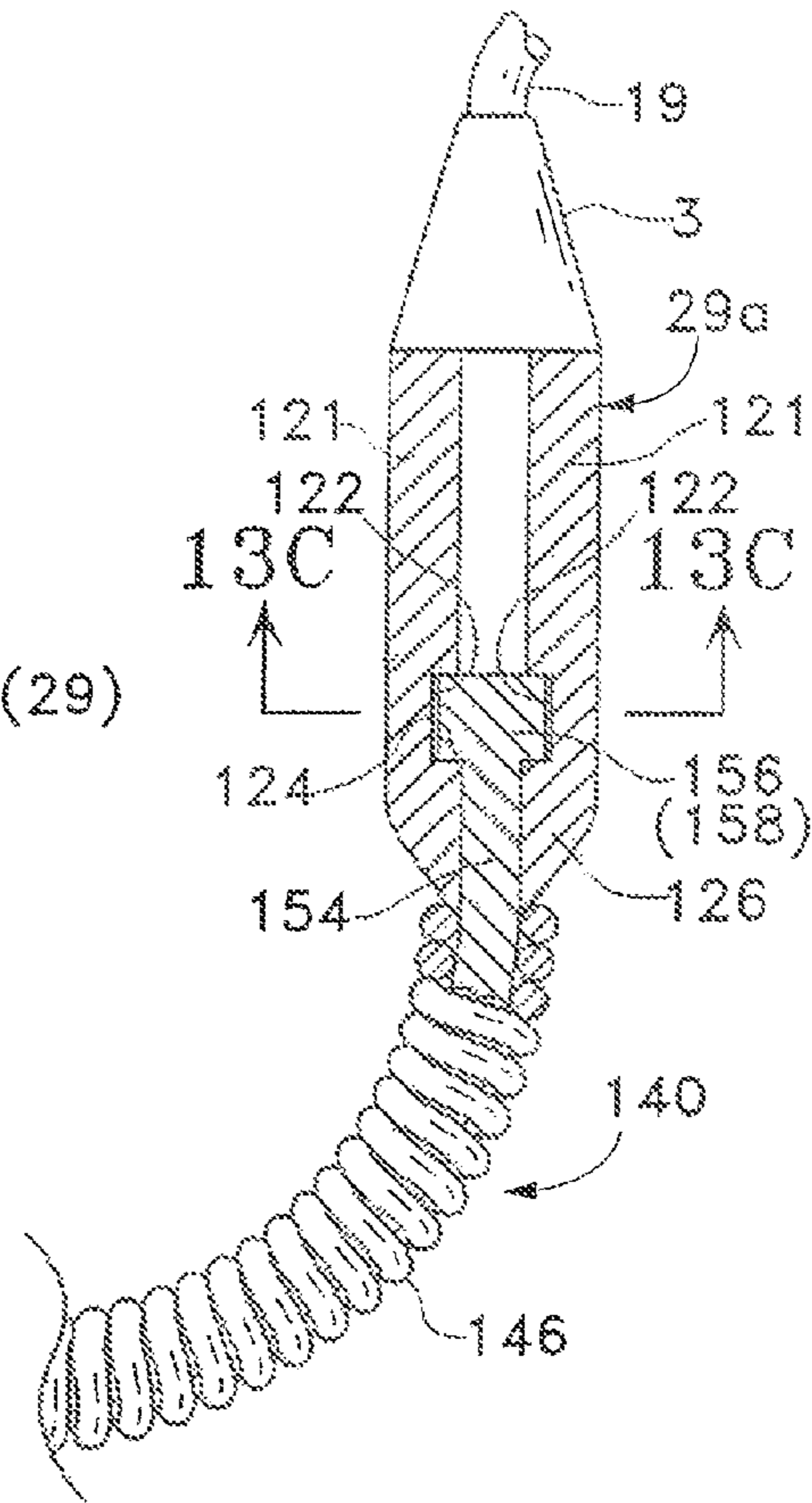
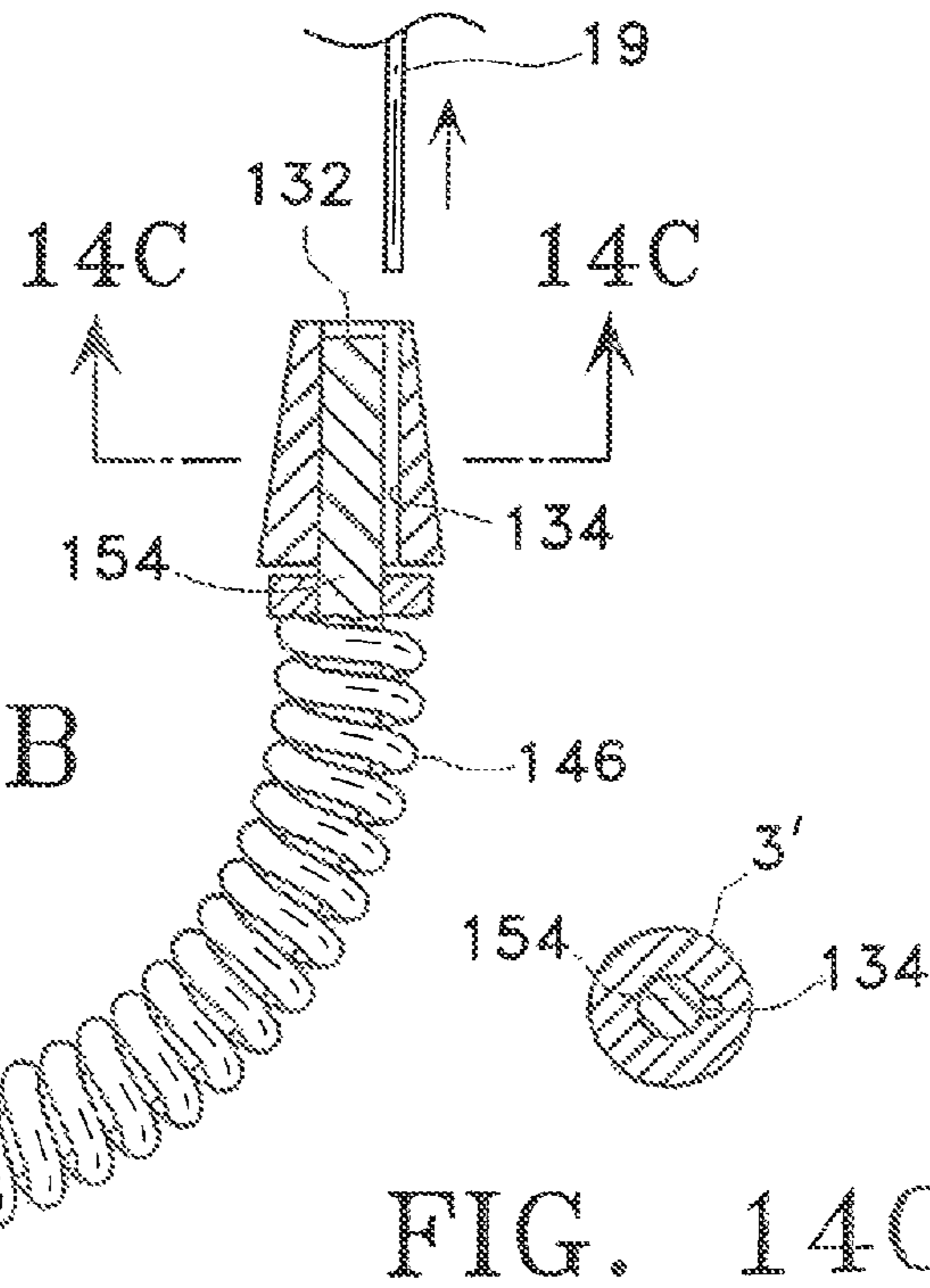
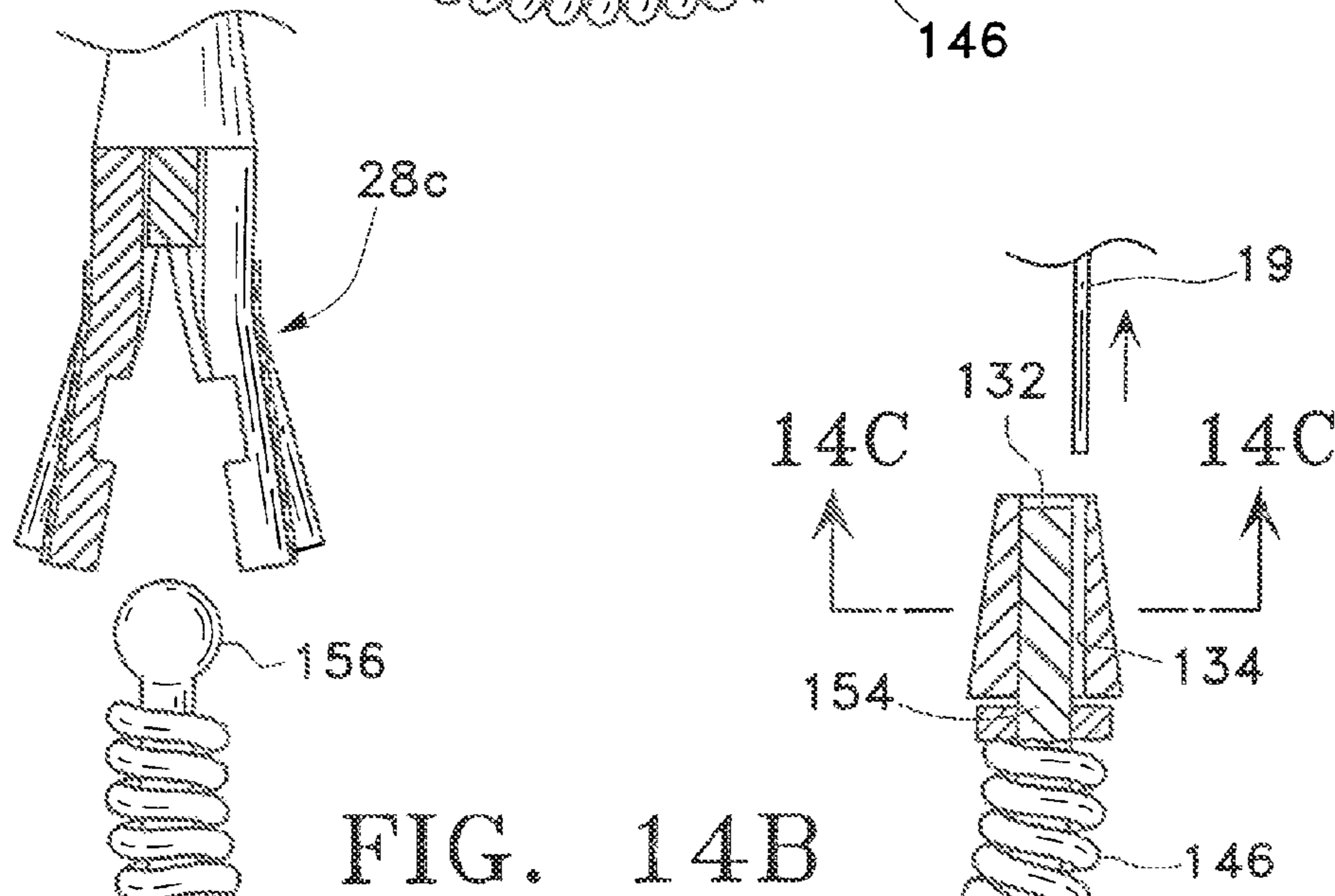
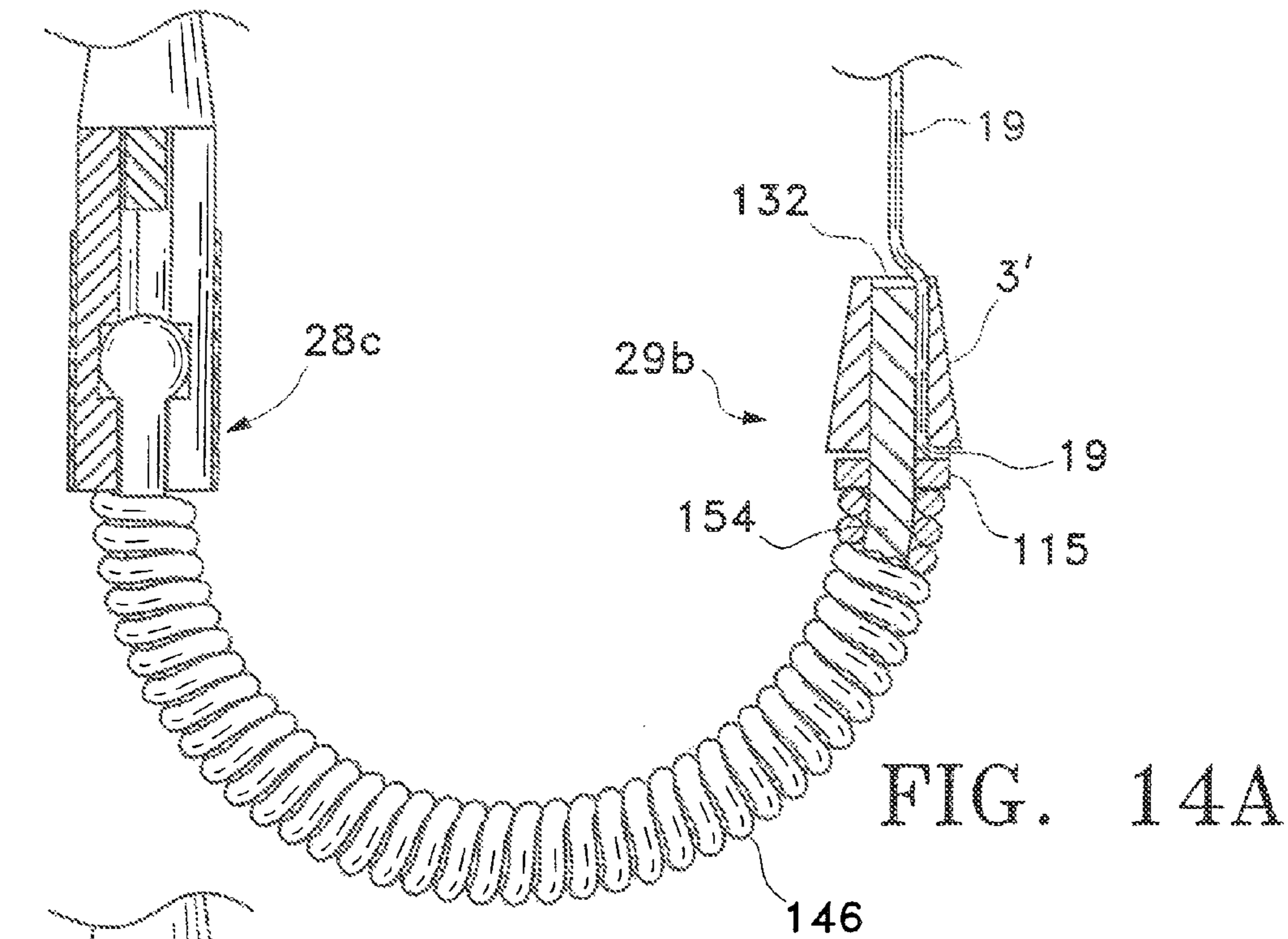


FIG. 13C



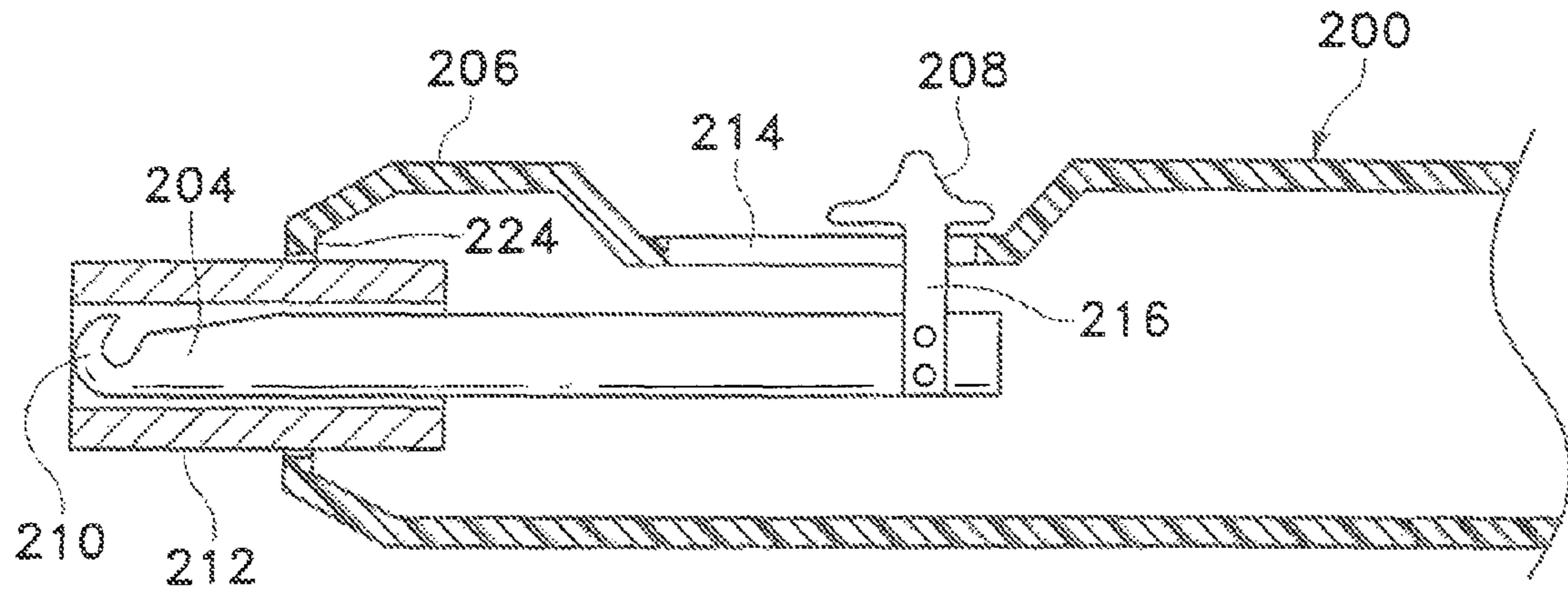


FIG. 15A

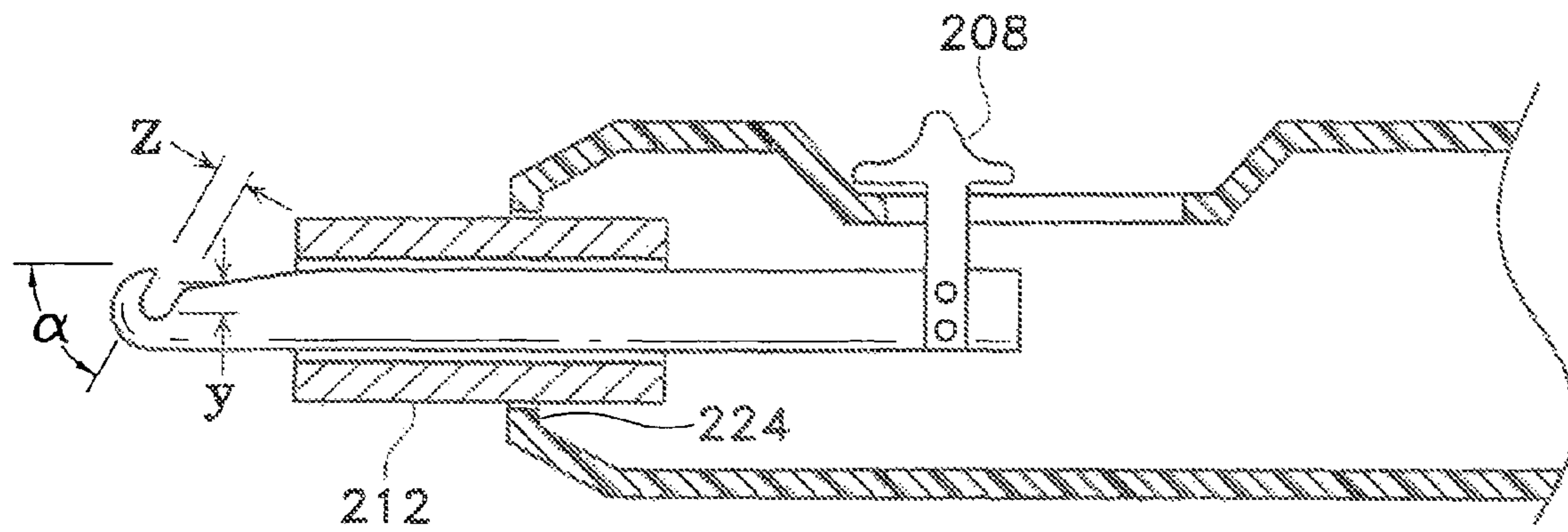


FIG. 15B

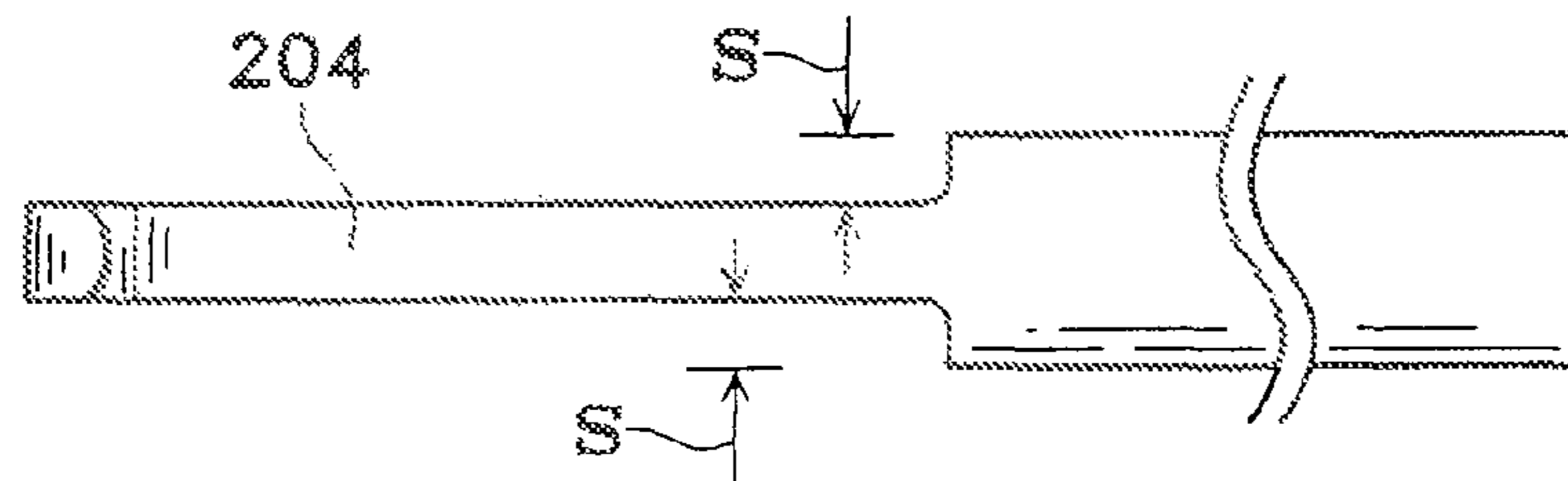


FIG. 15C

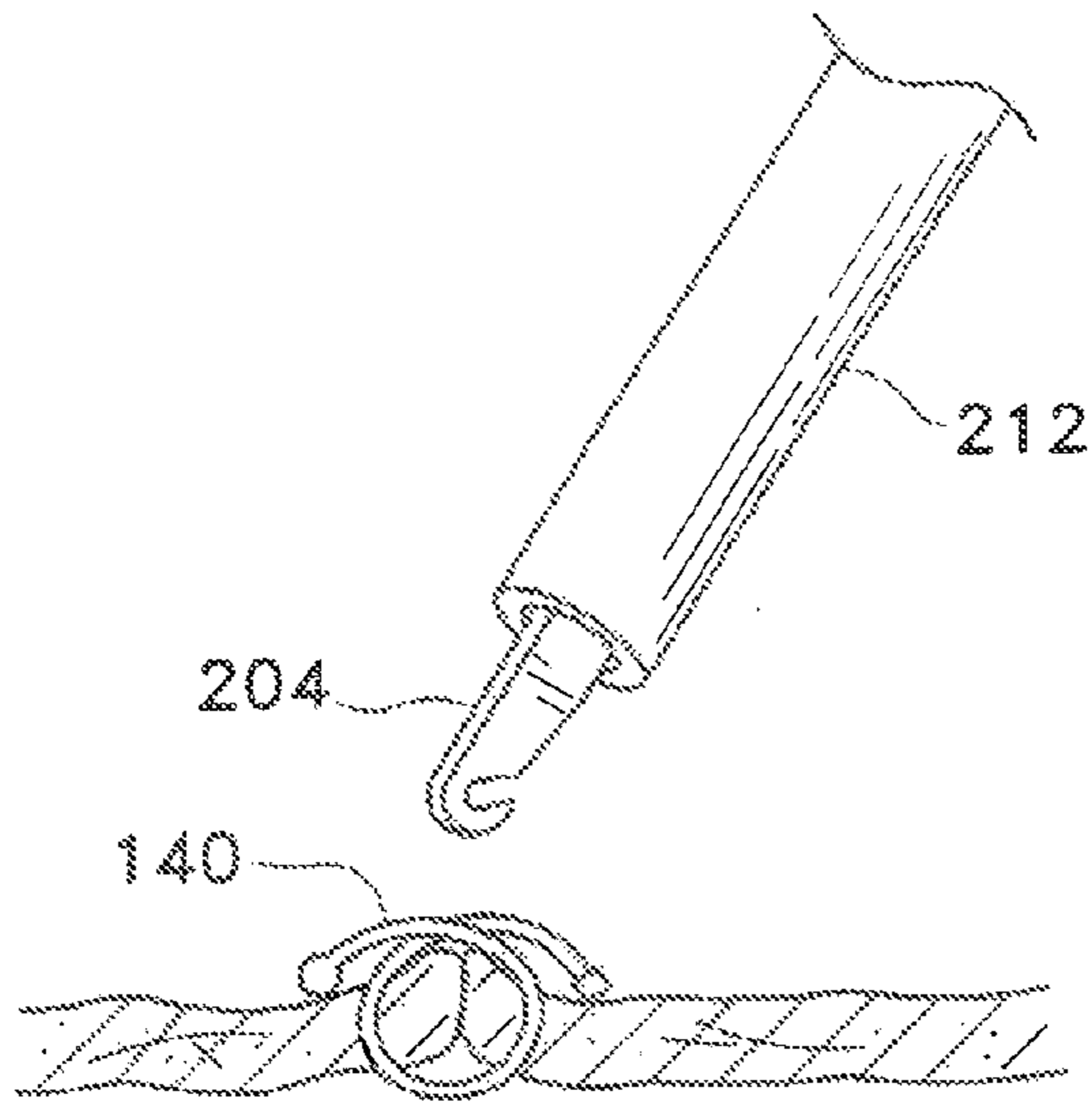


FIG. 16A

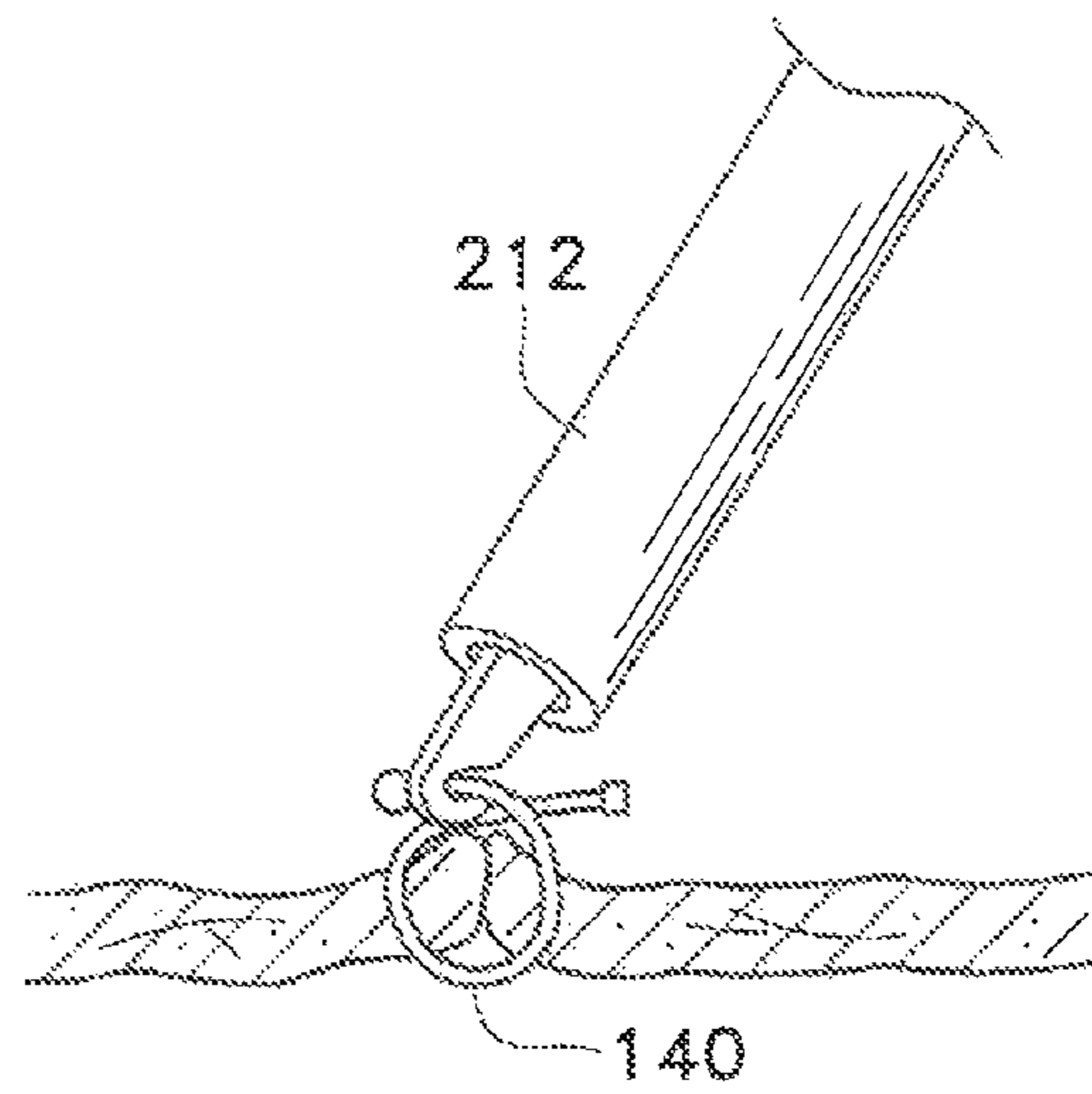


FIG. 16B

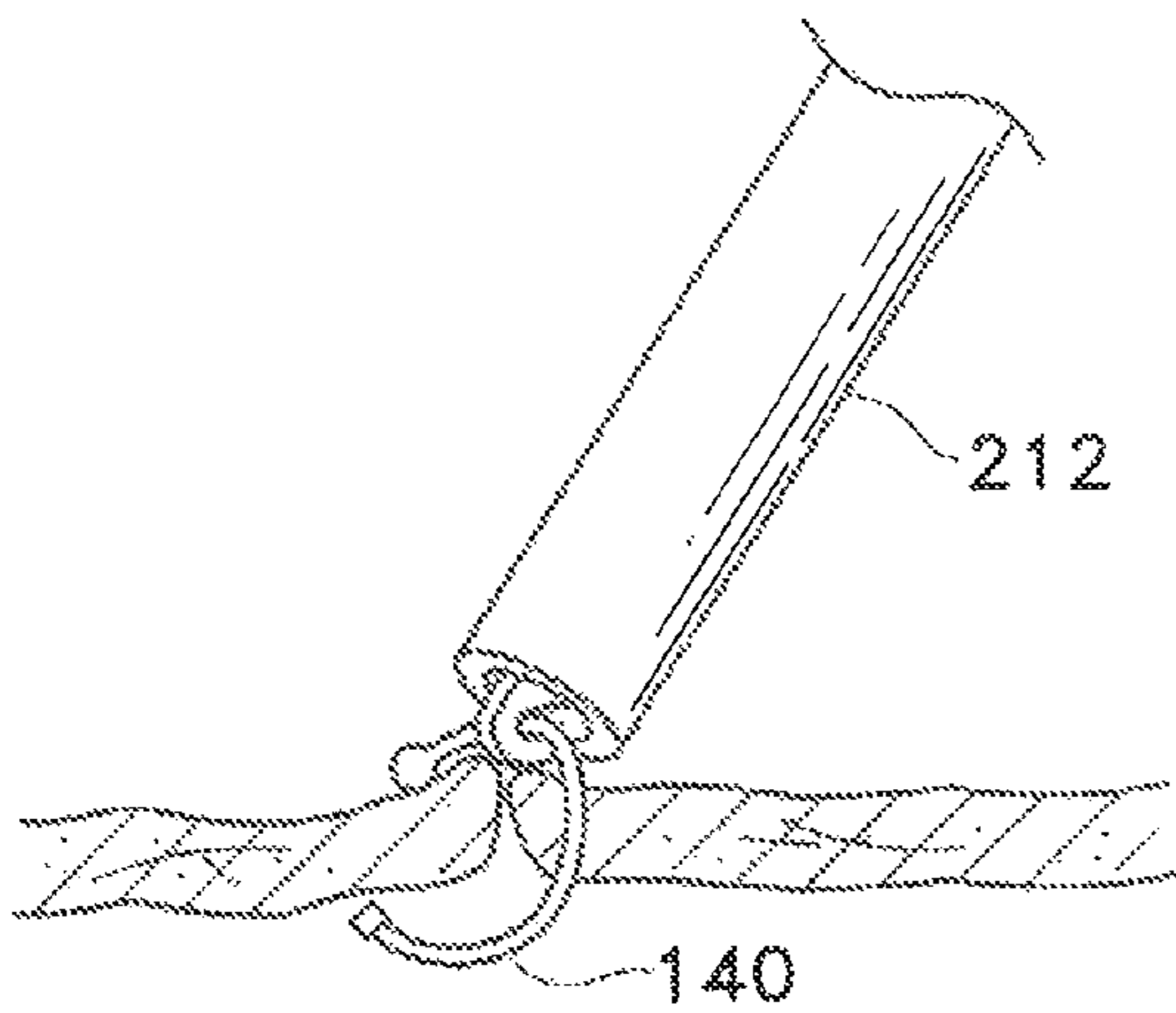


FIG. 16C

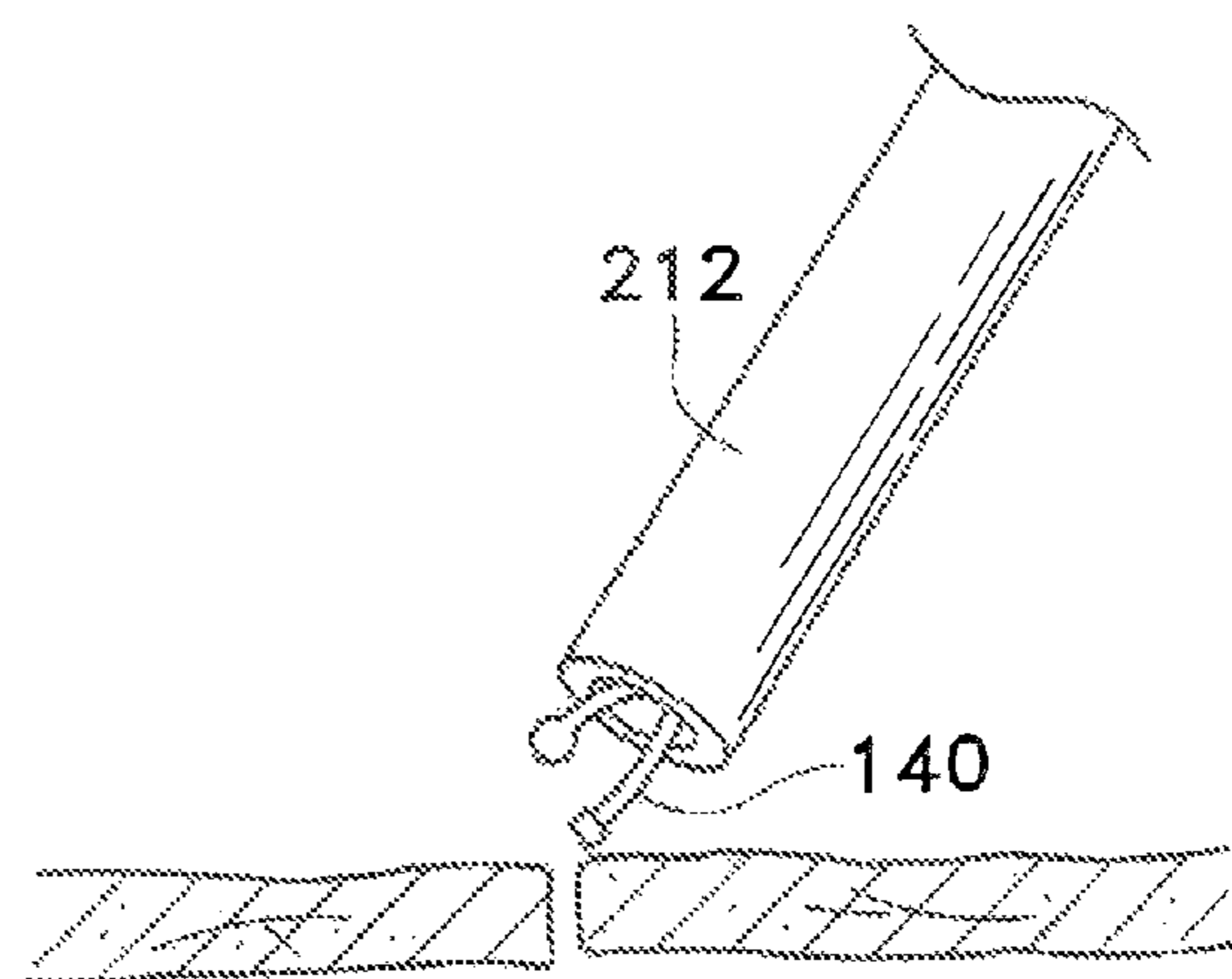


FIG. 16D

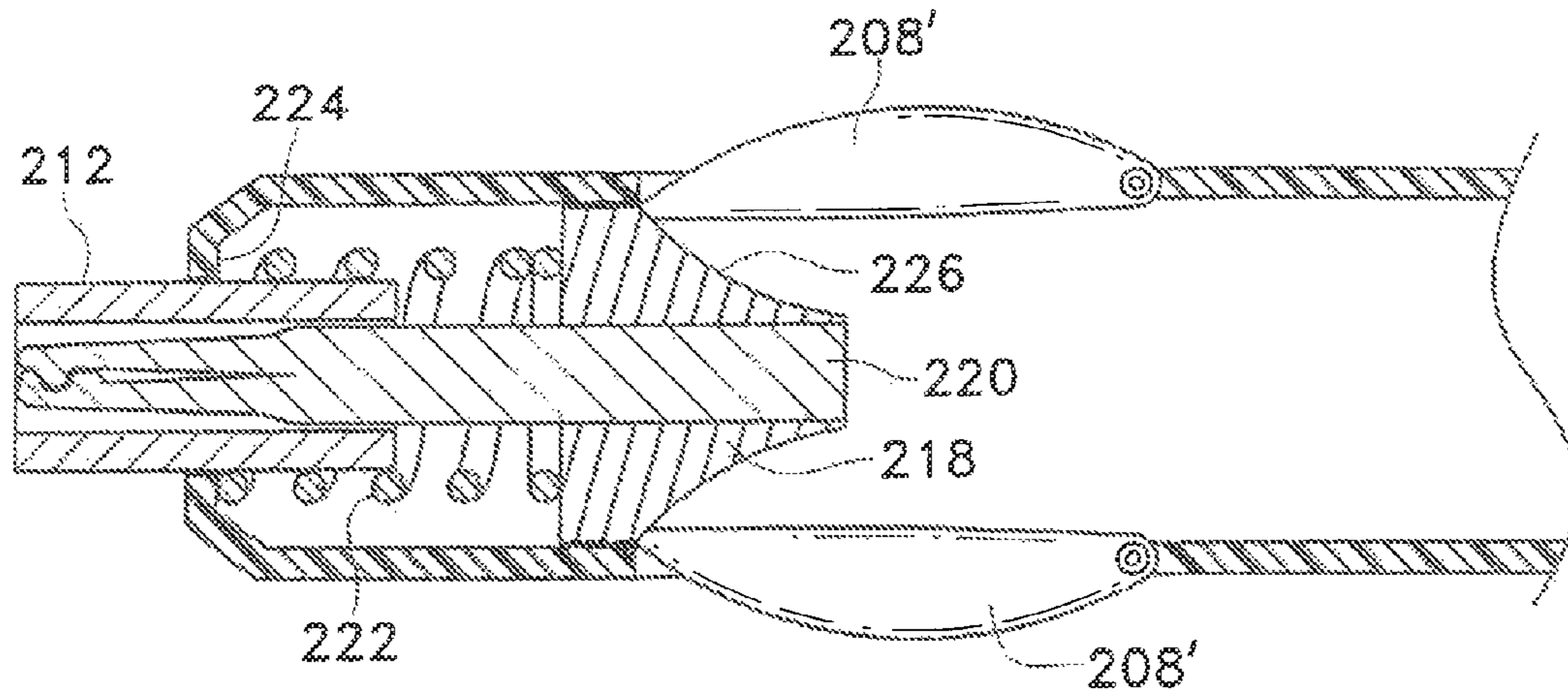


FIG. 17A

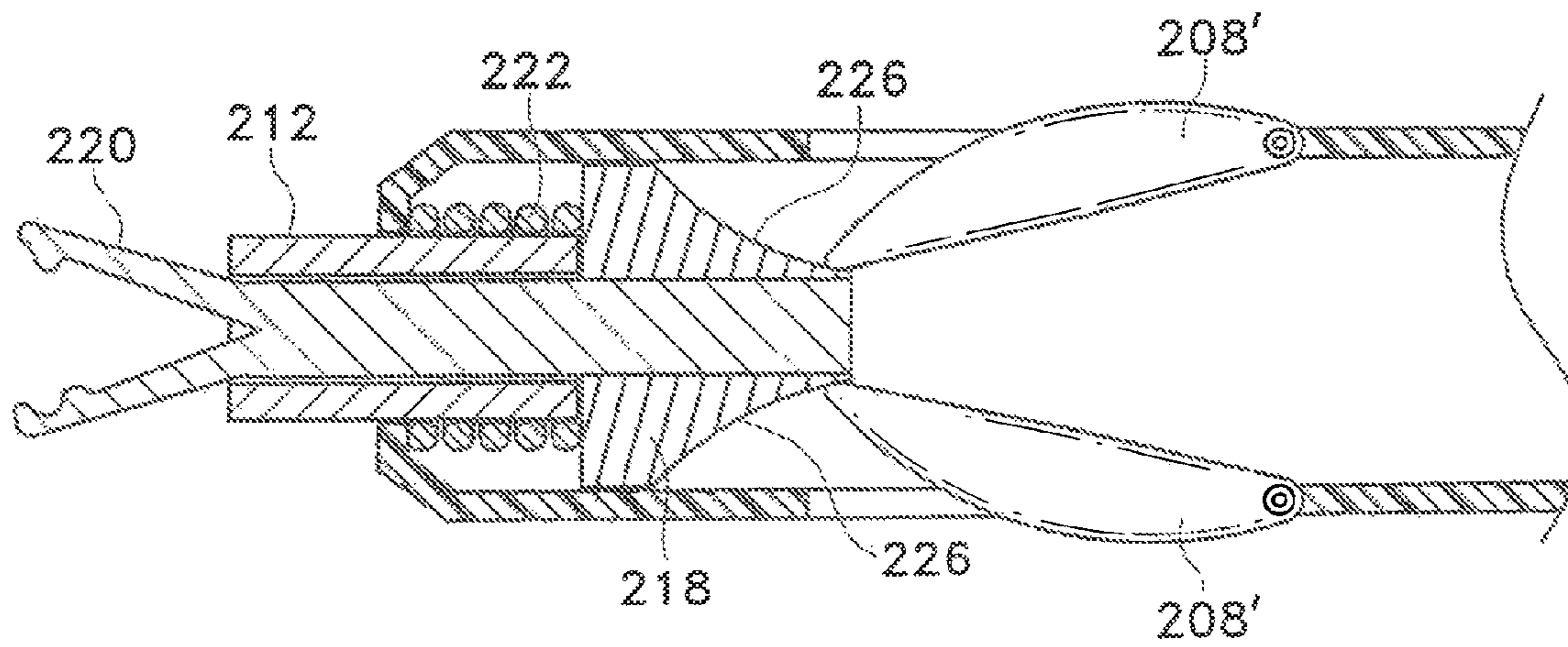


FIG. 17B

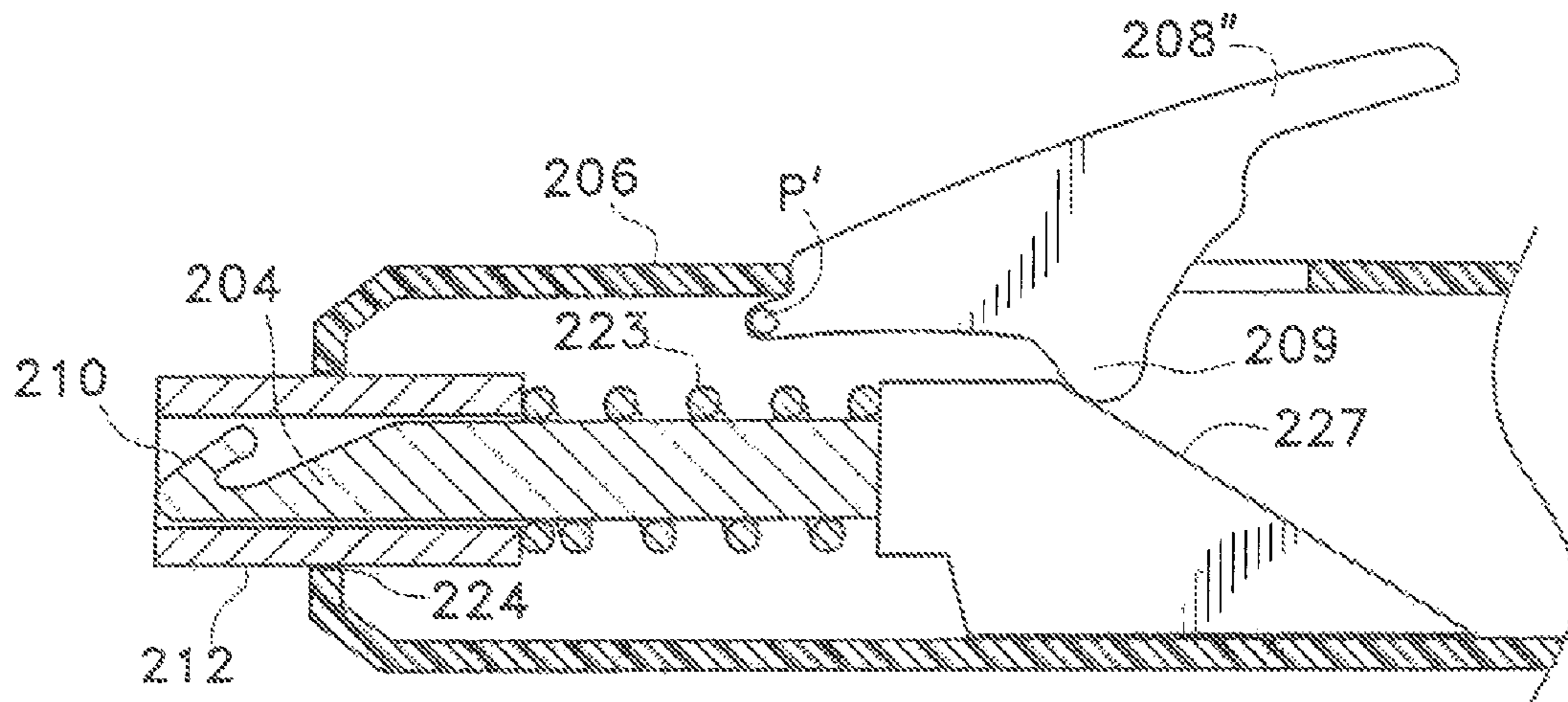


FIG. 17C

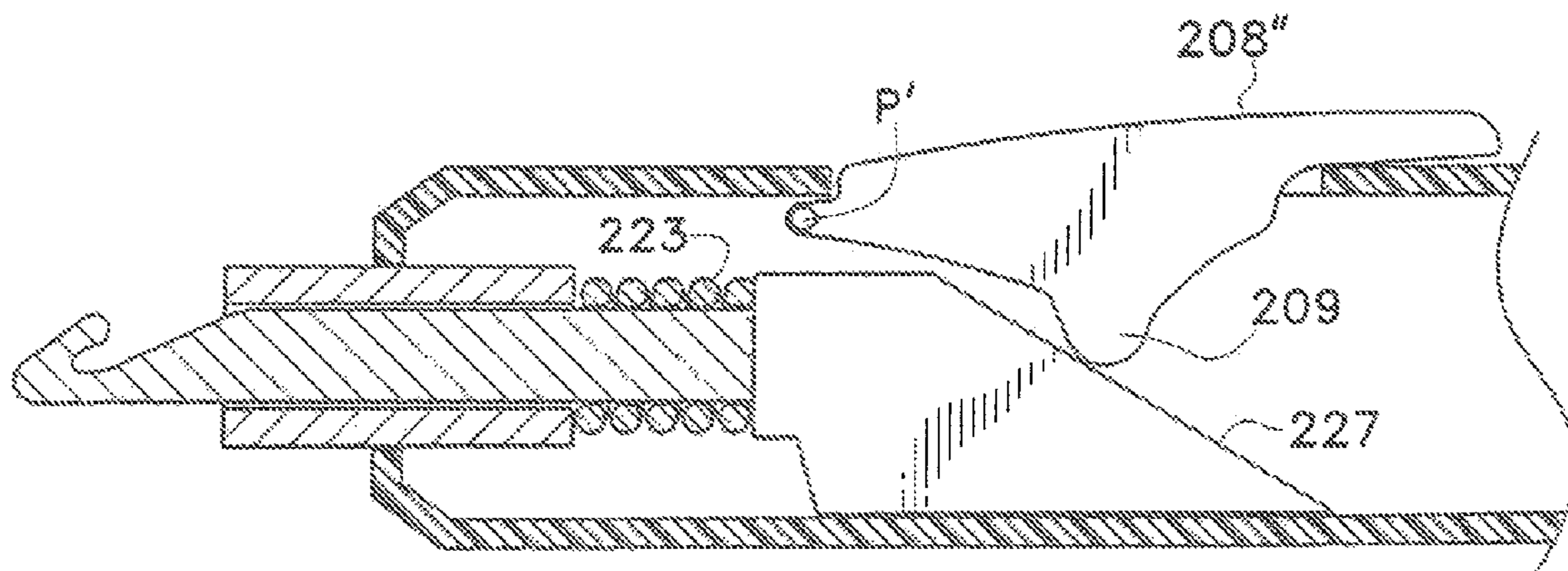


FIG. 17D

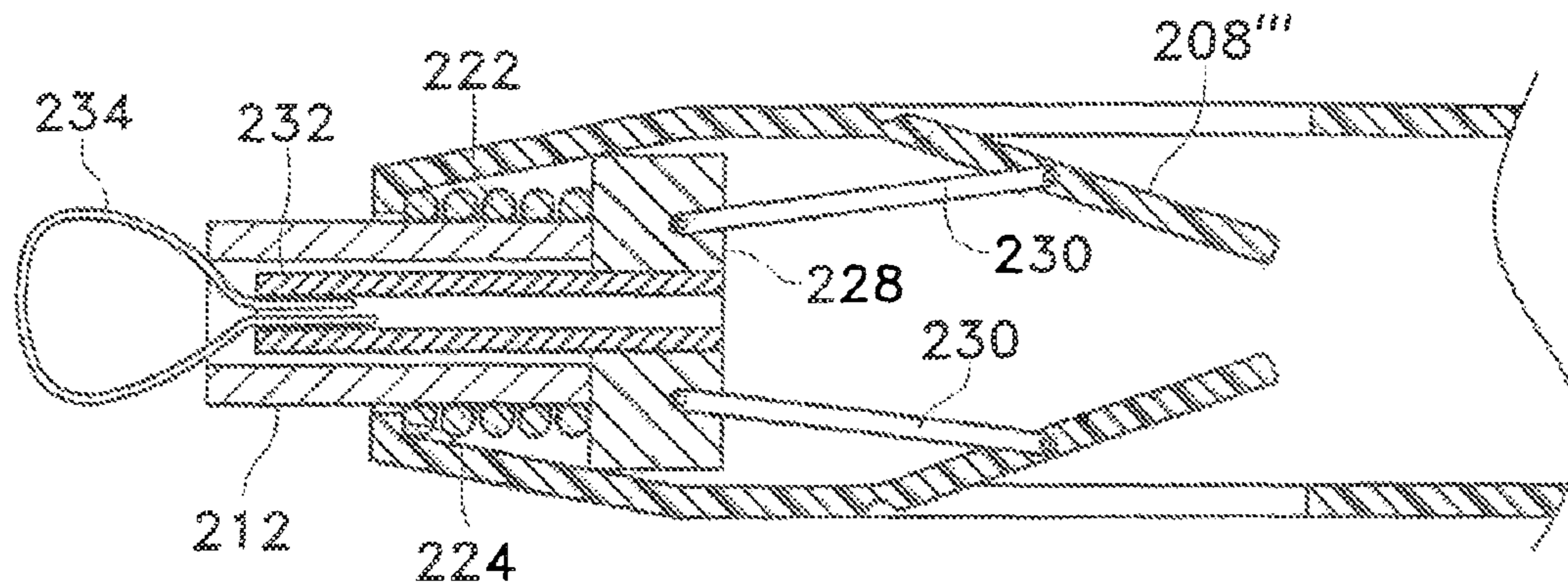


FIG. 18A

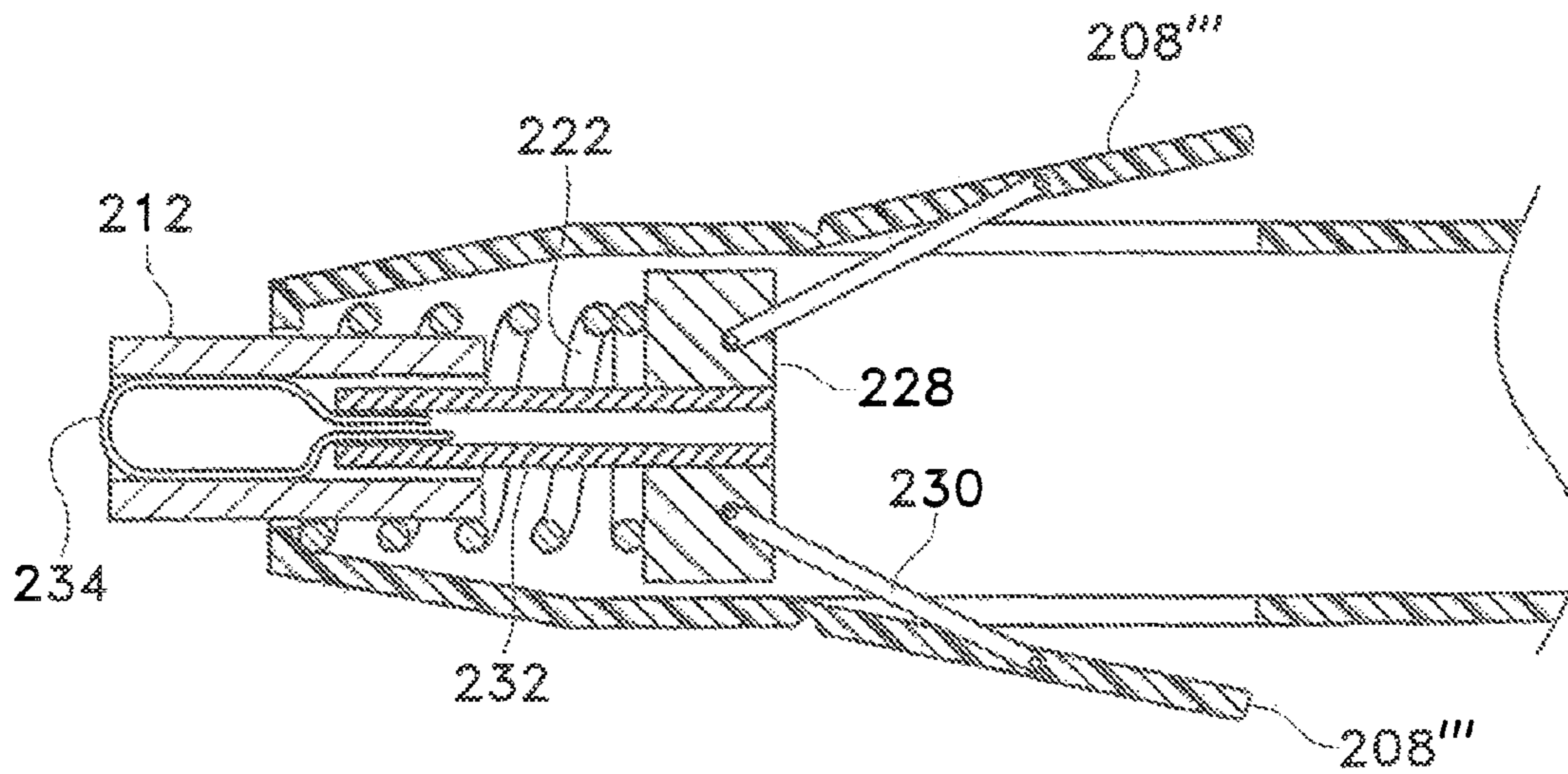


FIG. 18B

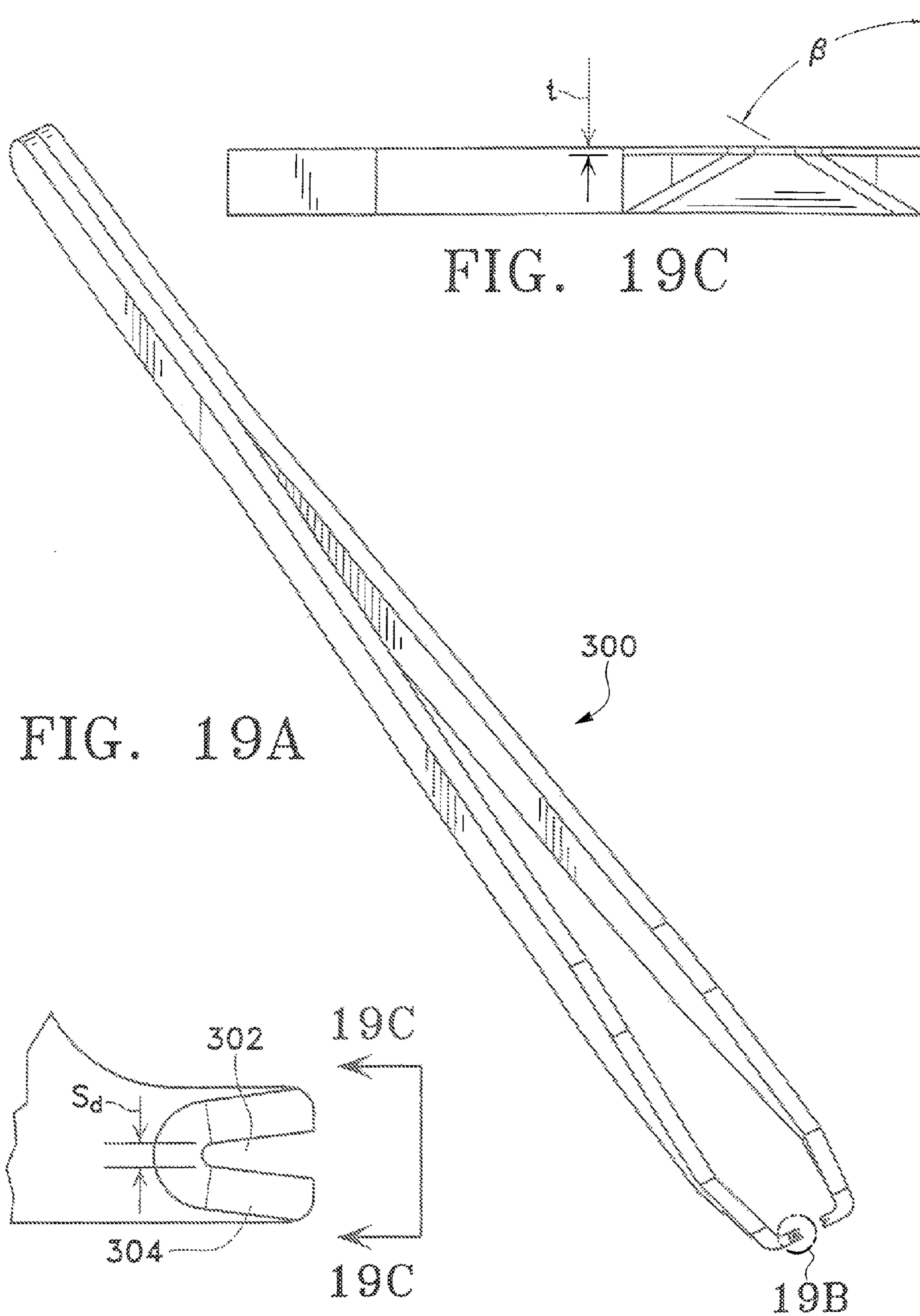


FIG. 19C

FIG. 19A

FIG. 19B

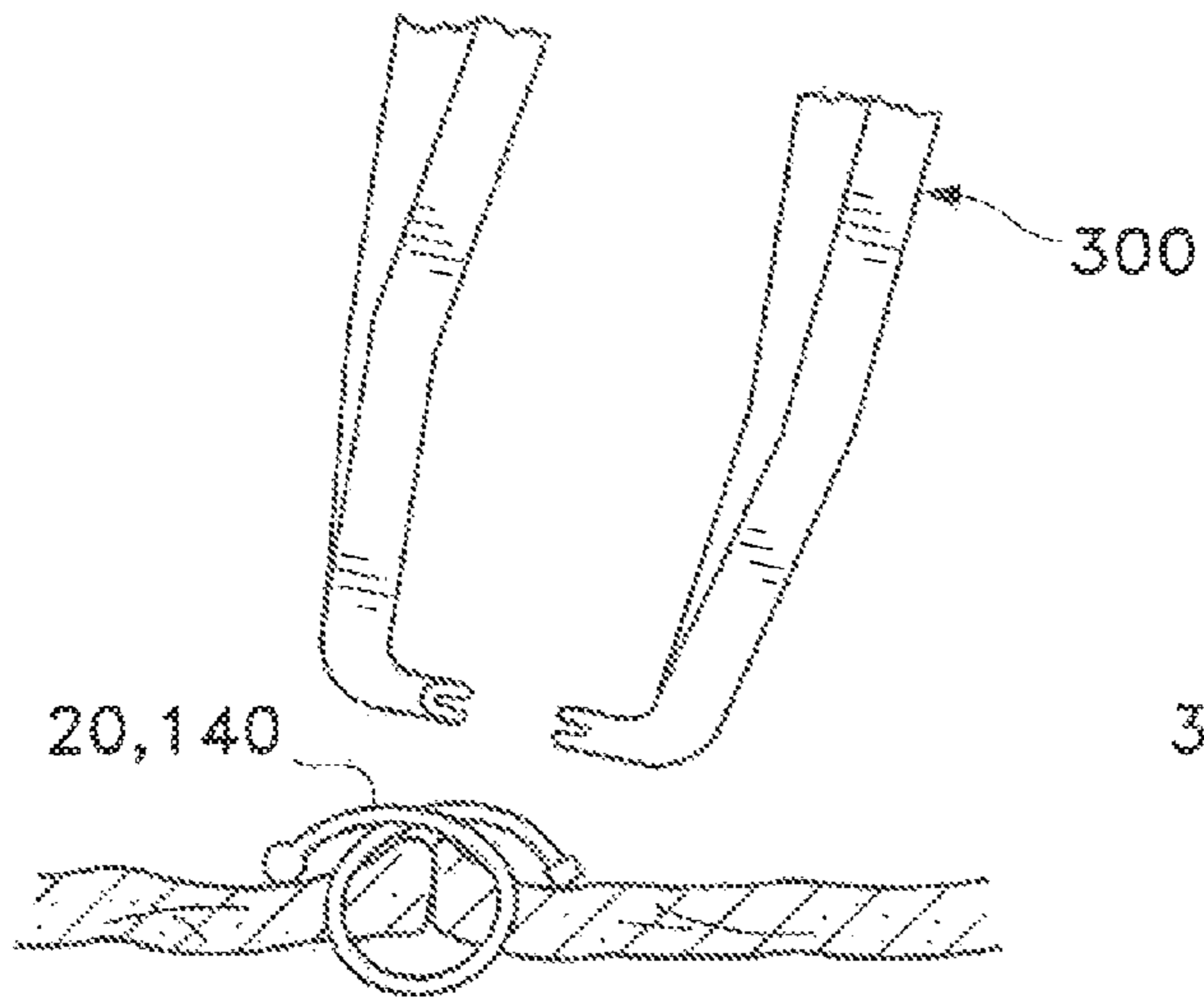


FIG. 20A

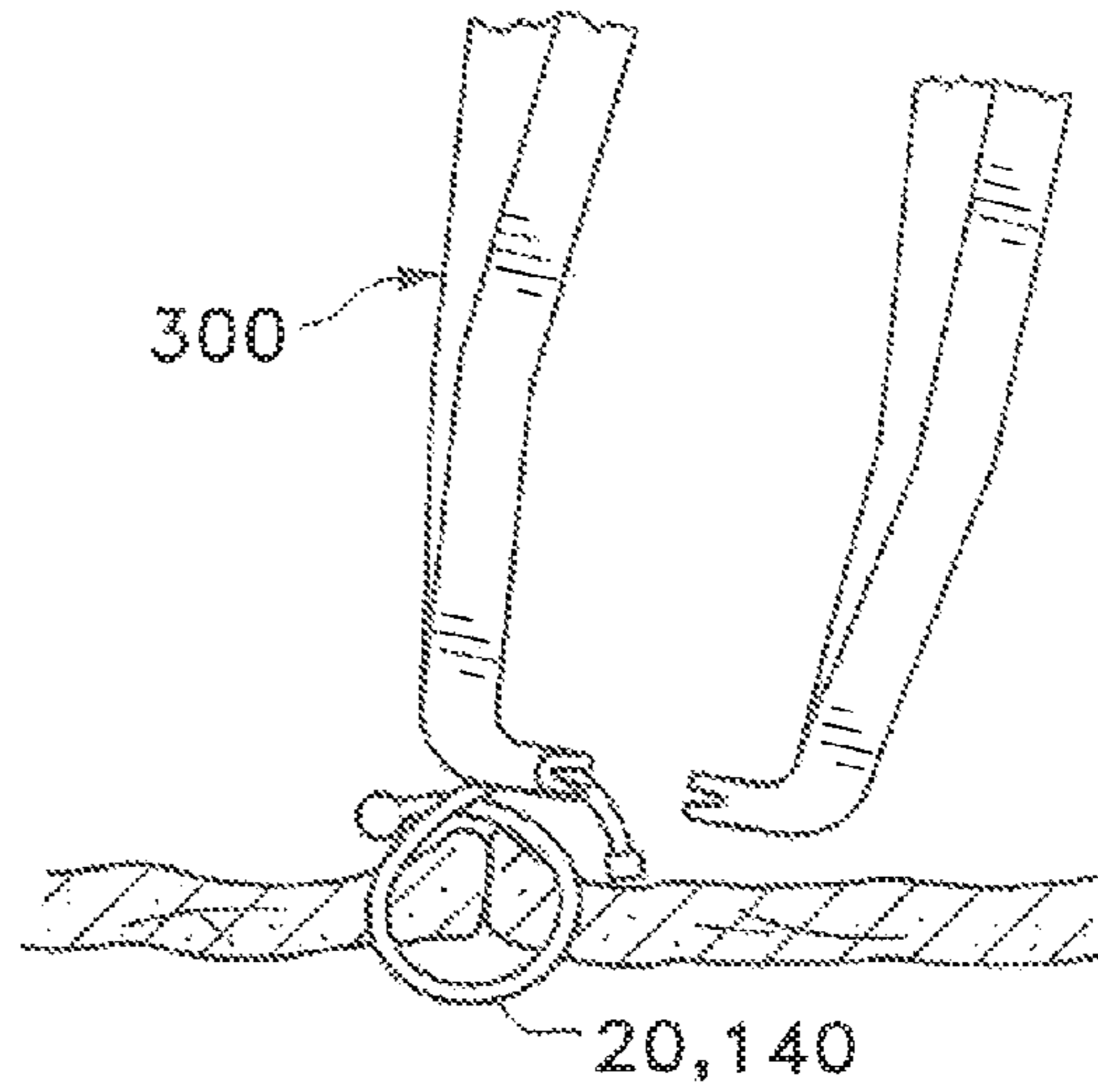


FIG. 20B

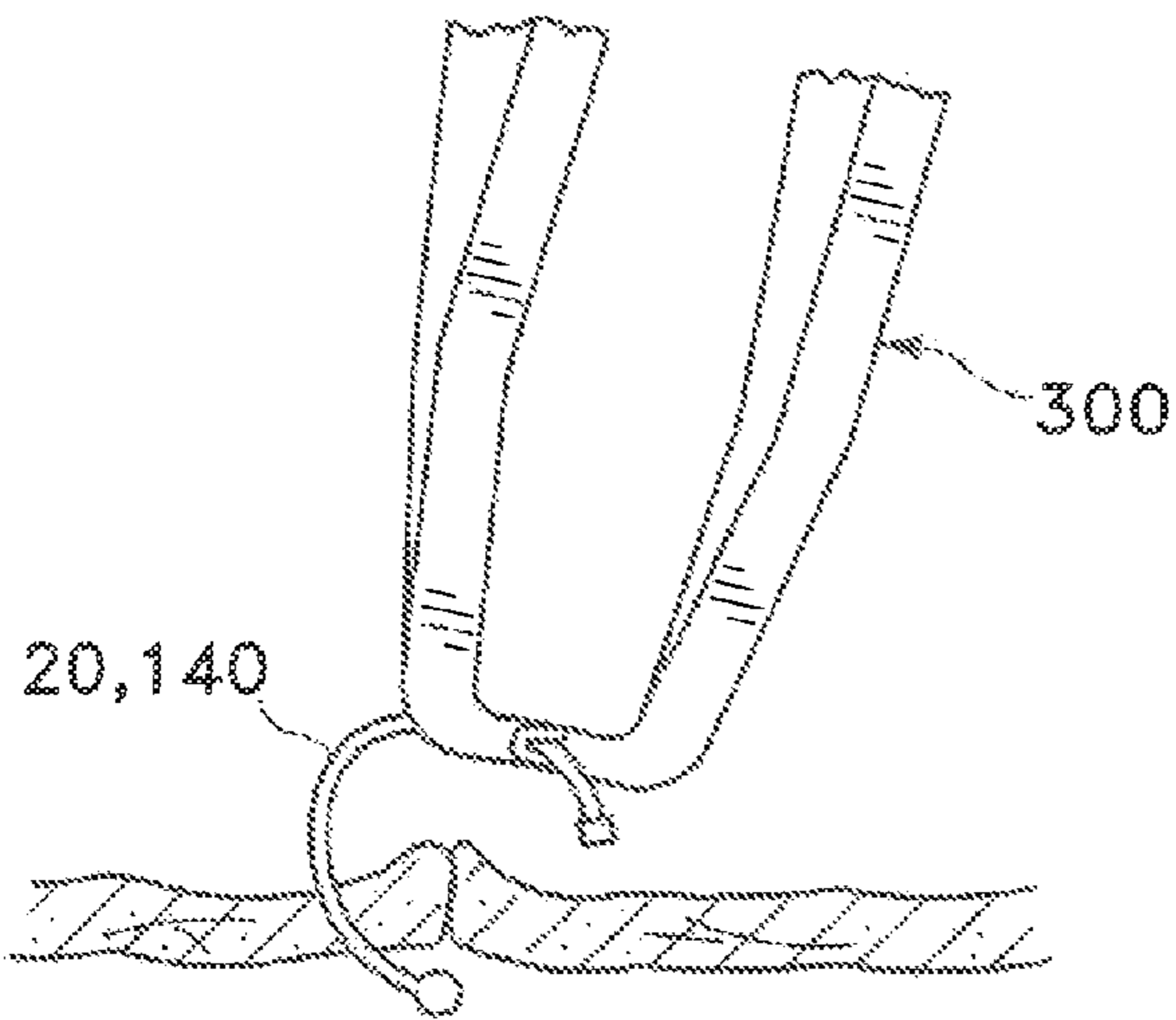


FIG. 20C

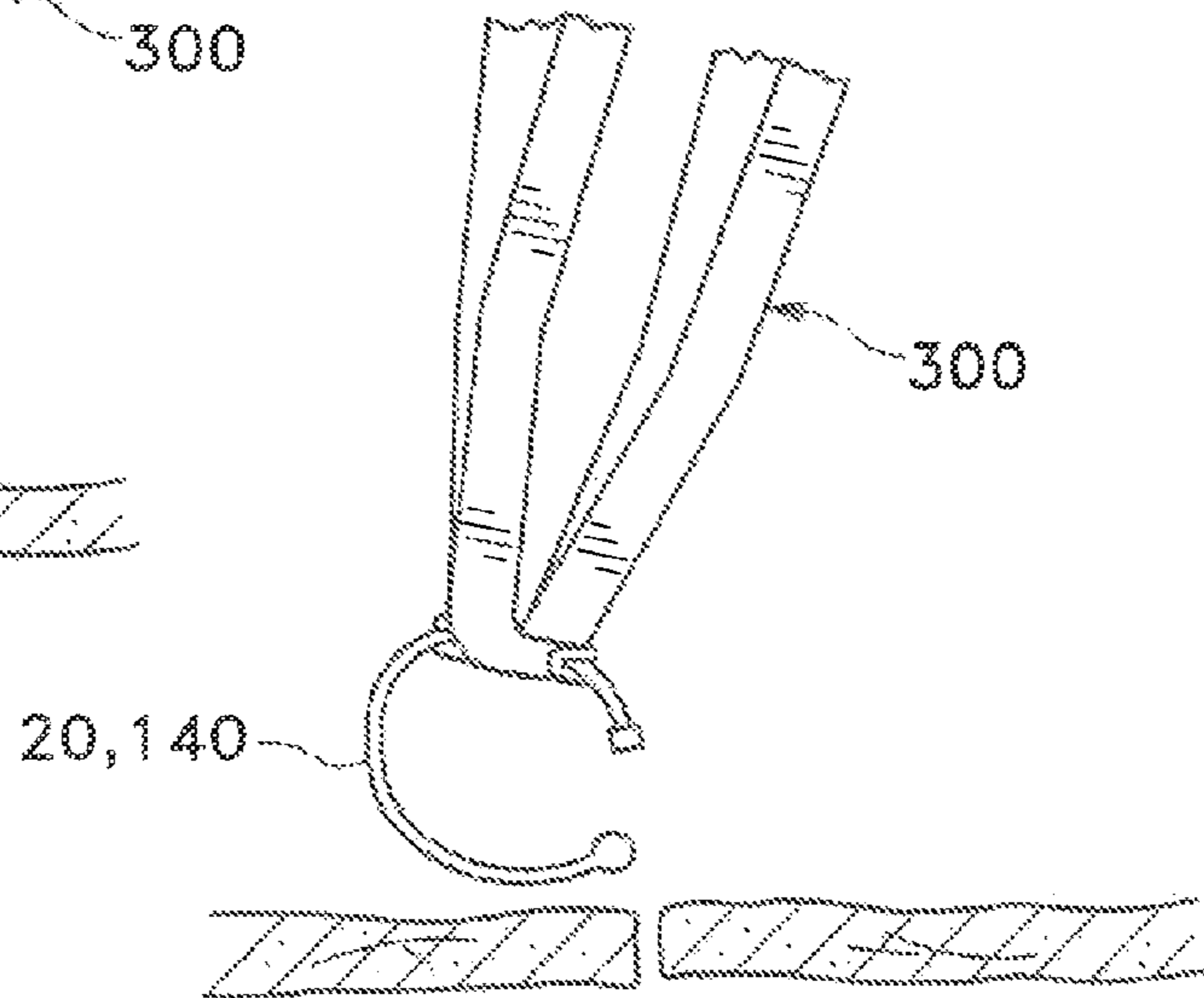
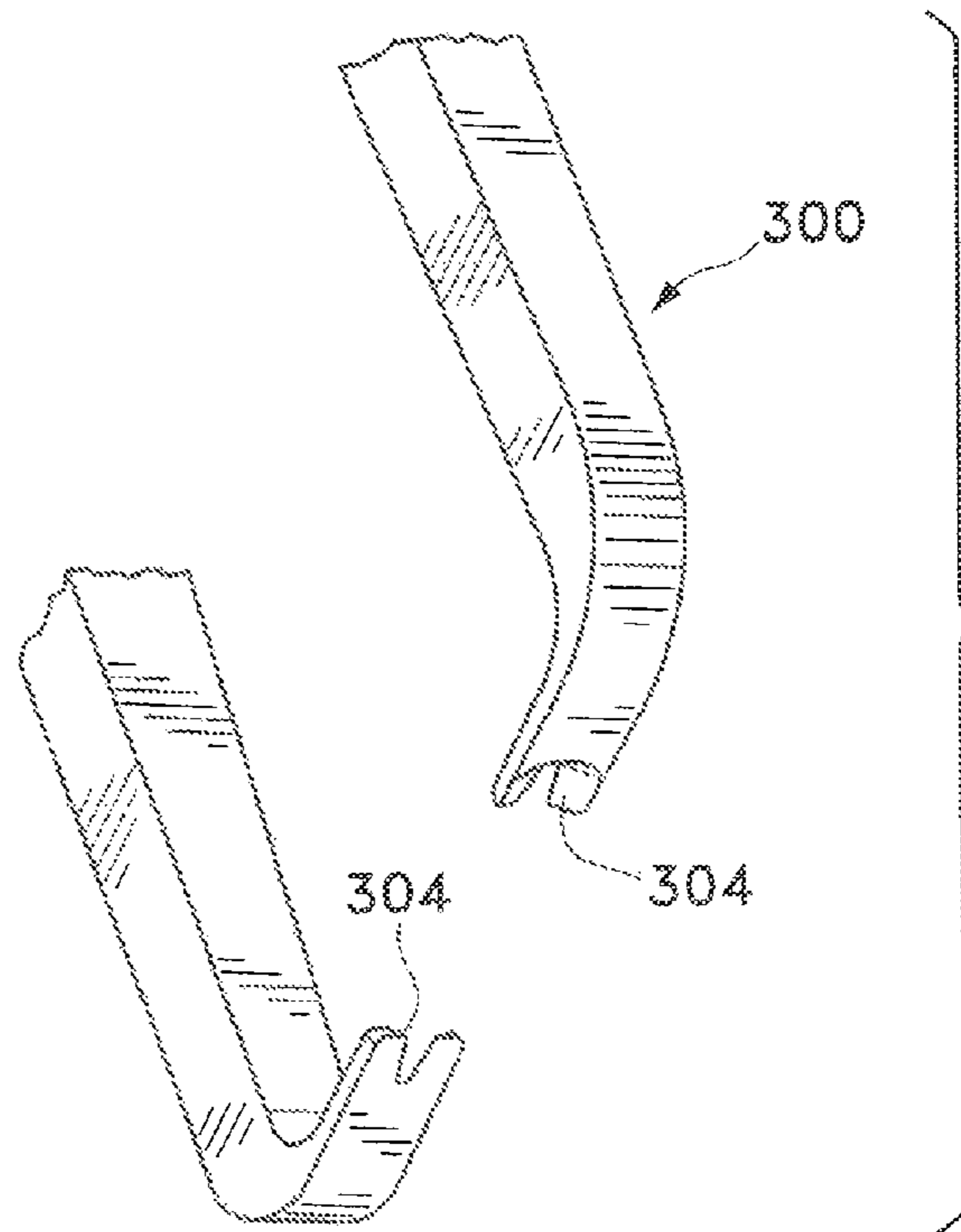
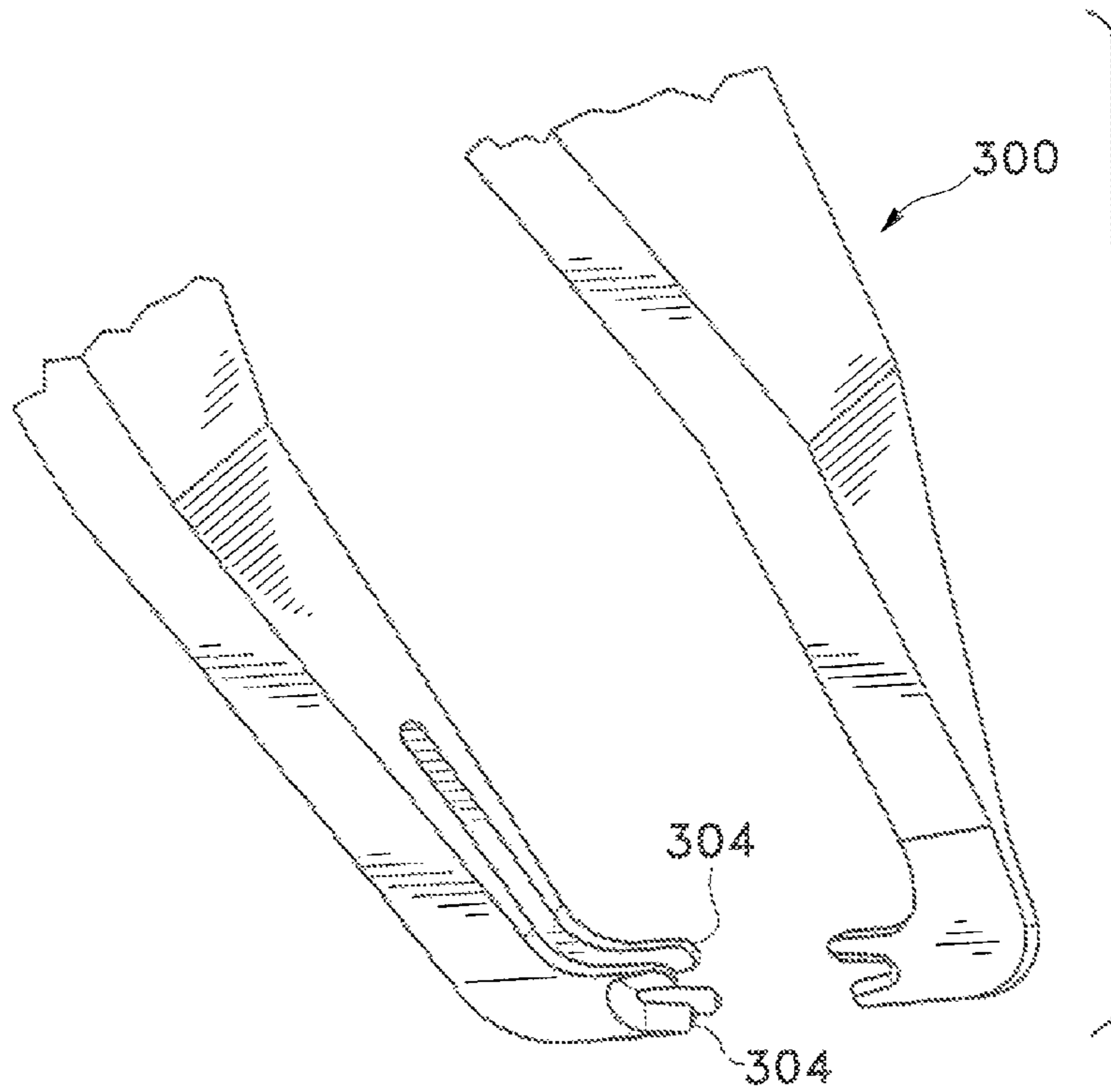


FIG. 20D



MULTIPLE BIAS SURGICAL FASTENERCROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a divisional of co-pending U.S. patent application Ser. No. 10/408,019, filed Apr. 3, 2003, which is a continuation of U.S. patent application Ser. No. 09/541,397, filed Mar. 31, 2000, now U.S. Pat. No. 6,551,332, issued Apr. 22, 2003, the entire contents of which are incorporated by reference herein.

TECHNICAL FIELD

The present invention relates to surgical fasteners for connecting body tissues, tissue and prostheses, tissue and graft or any combination thereof.

BACKGROUND

Minimally invasive surgery has allowed physicians to carry out many surgical procedures with less pain and disability than conventional, open surgery. In performing minimally invasive surgery, the surgeon makes a number of small incisions through the body wall to obtain access to the tissues requiring treatment. Typically, a trocar is delivered into the body with a cannula. After the trocar pierces into the body cavity, it is removed and the cannula is left with one end in the body cavity.

When a minimally invasive procedure is done in the abdominal cavity, the retroperitoneal space, or chest, the space in which the operation is performed is more limited, and the exposure to the involved organs is more restricted, than with open surgery. Moreover, in a minimally invasive procedure, the instruments used to assist with the operation are passed into the surgical field through cannulae. When manipulating instruments through cannulae, it is extremely difficult to position tissues in their proper alignment with respect to each other, pass a needle through the tissues, form a knot with the suture material once the tissues are aligned, and prevent the suture material from becoming tangled.

The fastening of body tissues together, or of fastening body tissues to graft materials becomes much more difficult in the restricted spaces imposed upon a surgeon when working through cannulae. Because the use of sutures is often difficult if not impossible in these situations, various other forms of fasteners have been developed to simplify the joining together of tissues and tissues with grafts in these environments, as well as in more conventional surgical procedures.

One variation of a suture is disclosed in U.S. Pat. No. 5,002,563, which forms surgical sutures from shape memory alloys. A suture is formed in the shape of a loop and a needle is affixed to an end thereof. A straight sleeve is provided to maintain the suture relatively straight as it is being inserted into the tissues to be joined. Removal of the sleeve allows the suture to return to its memorized loop shape. End segments of the loop can then be interlocked manually to secure the wound closure. Although this device is less cumbersome than tying conventional sutures, it still requires a coordinated effort to advance the suture into the tissues while removing the sleeve during the insertion process. Also, the interlocking step is similar to suturing, if not as difficult or complicated as tying a conventional suture. This device is disclosed for use in closure of deep wounds and there is no suggestion of use in close environments such as in minimally invasive surgical procedures.

PCT publication nos. WO 99/62406 and WO 99/62409, which are commonly assigned to the assignee of the present application, disclose tissue connector assemblies having a clip movable between an open state and a closed state and a mechanical restraining device attached to the clip for restraining the clip in its open state. The clip has a generally U-shaped configuration when in its open state. A needle may be releasably attached to the clip. This type of tissue connector assembly is discussed further below, with regard to FIGS. 4 and 5. PCT publication nos. WO 99/62406 and WO 99/62409 are incorporated herein, by reference thereto, in their entireties.

SUMMARY OF THE INVENTION

The present invention involves surgical fasteners having biasing members which aid in the closure of the fasteners, and methods of making such fasteners. A fastener, according to the present invention, includes a clip movable between an open configuration and a closed configuration, and a biasing member contacting the clip and biased to conform to the closed configuration when in a free state. The biasing member may be applied to form an integrated system with the clip, such that the biasing member and clip actuate in concert to close the fastener, thereby providing an optimal fastener configuration exhibiting an optimal closing force.

Additionally, the clip is biased to conform to the closed configuration when in a free state. The clip may comprise a wire having a shape memory which defines a closed configuration, which may be substantially spiral-shaped, or another shape.

The biasing member may comprise a coil surrounding at least a portion of the clip, and may be a double coil. The biasing member may reside between two restraints located on the clip. Further, a release mechanism may be provided which is adapted to engage the clip at at least one of the restraints and to bias the biasing member to force the clip into the open configuration.

A method of making a surgical fastener according to the present invention includes winding a clip, formed of a shape memory material, into a predetermined closed configuration; setting the clip into the predetermined closed configuration so that the clip has a memory configuration which is the predetermined closed configuration; and conforming a biasing member to the clip in the predetermined closed configuration; setting the clip and biasing member into the predetermined closed configuration to form a fastener comprising the clip and the biasing member wherein each has a memory configuration which is the predetermined closed configuration.

The clip and biasing member may each be set by heating at a predetermined temperature for a predetermined time, and the combination of these components may further be set by heating at a predetermined temperature for a predetermined time.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a view of a surgical fastener according to the present invention;

FIGS. 1B and 1C show a variation of the fastener of FIG. 1A;

FIG. 2 is a view of a clip, absent of any biasing member, in a closed configuration;

FIG. 3A shows a single coil set in an axially straight configuration;

FIG. 3B shows a double coil set in an axially straight configuration;

FIG. 4 shows a prior art fastener in an open configuration;

FIG. 5 shows the fastener of FIG. 4 in a closed configuration;

FIG. 6 shows the positioning of a coil over a clip for setting the closed configuration of a fastener;

FIG. 7 shows a fastener according to the present invention in an open configuration;

FIG. 8 shows a double coil which is set into a closed configuration;

FIG. 9 is a tissue connector assembly, which may include the fastener of any of FIGS. 1-8;

FIGS. 10A and 10B are sectional views of a fastener release mechanism, which may be used in the assembly of FIG. 9;

FIGS. 11A, 11B and 11C diagrammatically illustrate the placement of fasteners in an anastomosis;

FIG. 12 shows a double needle tissue connector assembly;

FIG. 13A shows a release mechanism that may be used with the second needle in the assembly of FIG. 12;

FIGS. 13B and 13C show another release mechanism that may be used with the second needle in the assembly of FIG. 12, where FIG. 13C is a sectional view of FIG. 13B taken along line 13C-13C;

FIGS. 14A, B and C show another release mechanism that may be used with the second needle in the assembly of FIG. 12, where FIGS. 14A and 14B are partial sectional views of the system in a coupled and decoupled state, respectively, and FIG. 14C is a transverse cross-sectional view taken along line 14C-14C in FIG. 14B;

FIGS. 15A, 15B and 15C show fastener removal apparatus which may be used with the present invention where FIGS. 15A and 15B are sectional views and FIG. 15C is a top view of the elongated grabber member of FIGS. 15A and 15B;

FIGS. 16A, 16B, 16C and 16D diagrammatically illustrate removal of a fastener with the apparatus of FIGS. 15A-C;

FIGS. 17A and 17B are sectional views of another embodiment of the fastener removal apparatus;

FIGS. 17C and 17D are sectional views of a variation of the cam mechanism of FIGS. 17A and 17B in combination with the hooked fastener grabber of FIGS. 15A-C;

FIGS. 18A and 18B are sectional views of another embodiment of a fastener removal apparatus that may be used with the present invention;

FIGS. 19A, 19B and 19C show another embodiment of a fastener removal apparatus that may be used with the present invention;

FIGS. 20A, 20B, 20C and 20D diagrammatically illustrate removal of a fastener using the apparatus of FIGS. 19A-C;

FIG. 21 shows a variation on the apparatus of FIGS. 19A-C; and

FIG. 22 shows another variation on the apparatus of FIGS. 19A-C.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

Tissue connectors such as those discussed in PCT publication nos. WO 99/62406 and WO 99/62409, as described above are also disclosed in currently copending and commonly assigned application Ser. No. 09/090,305, filed Jun. 3, 1998, which is incorporated herein, by reference thereto, in its entirety. Referring to FIG. 4, a fastener (e.g., fastener 20) such as that described in application Ser. No. 09/090,305 comprises a deformable wire 34 made of a shape memory alloy. A nickel titanium (e.g., Nitinol) based alloy may be used, for example. The Nitinol may include additional elements which affect the yield strength of the material or the temperature at

which particular pseudoelastic or shape transformation characteristics occur. The transformation temperature may be defined as the temperature at which a shape memory alloy finishes transforming from martensite to austenite upon heating (i.e., A_f temperature). The shape memory alloy preferably exhibits pseudoelastic (superelastic) behavior when deformed at a temperature slightly above its transformation temperature. At least a portion of the shape memory alloy is converted from its austenitic phase to its martensitic phase when the wire is in its deformed configuration. As the stress is removed, the material undergoes a martensitic to austenitic conversion and springs back to its original undeformed configuration. When the wire is positioned within the tissue in its undeformed configuration, a residual stress is present to maintain the tissue tightly together. In order for the pseudoelastic wire to retain sufficient compression force in its undeformed configuration, the wire should not be stressed past its yield point in its deformed configuration to allow complete recovery of the wire to its undeformed configuration. The shape memory alloy is preferably selected with a transformation temperature suitable for use with a stopped heart condition where cold cardioplegia has been injected for temporary paralysis of the heart tissue (e.g., temperatures as low as 8-10 degrees Celsius).

It is to be understood that the shape memory alloy may also be heat activated, or a combination of heat activation and pseudoelastic properties may be used, as is well known by those skilled in the art.

The cross-sectional diameter of the wire and length of the wire will vary depending on the specific application. The diameter "d" of wire 34 may be, for example, between 0.001 and 0.015 inch. For coronary bypass applications, the diameter is preferably between 0.001 and 0.008 inch with a diameter D_1 of the loop (FIG. 5) being between 0.0125 and 0.0875 inch. As shown in FIGS. 2 and 5, the wire 34 may have a circular cross-sectional shape and a generally spiral shaped configuration when in a closed position. The diameter D_1 of the loop of the fastener 20, with coil 26, in its closed position is preferably sized to prevent movement between adjacent tissues. It is to be understood, however, that the wire may have other cross-sectional shapes such as rectangular, or may be formed from multiple strands.

One end of wire 34, may include an enlarged portion 36 having a cross-sectional area greater than the cross-sectional area of the wire and diameter of the coil to resist the coil from passing thereover. Alternatively, enlarged portion 36 may have a cross-section that allows the coil to be pulled over the enlarged portion. For example, the cross sectional diameter of the enlarged portion may be about equal to the inside diameter of the coil. The enlarged portion 36 also may be provided to cooperate with a release mechanism, which is described in further detail with reference to the present invention below.

In making the fastener 20, the wire 34 is first formed in the generally spiral shaped configuration shown in FIG. 2. The wire 34 may be formed in the above described shape by first wrapping the wire onto a mandrel and heat treating the wire at approximately 400-550 degrees Celsius for approximately 5 to 30 minutes. The wire 34 is then air quenched at room temperature. The mandrel may have a constant diameter or may be conical in shape, to facilitate forming the spiral configuration shown in FIG. 5. Other shapes are possible as described in application Ser. No. 09/090,305. Coil 26 is formed by wrapping a wire around a cylindrical mandrel (not shown) thereby cold-working the wire into a coil shape having a straight axial configuration as shown in FIG. 3. Next, the coil 26 is axially slid over the wire 34 whereupon it takes on the substantially spiral shaped configuration of the wire 34.

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Next, a locking device such as **28a**, for example (FIG. 4) is locked in position over enlarged portion **36**. Afterwards, an additional enlarged portion **38** is slid on the wire **34** and driven against the coil **26** to compress the same and open the fastener. When in the open position, the enlarged portion **38** is then fixed to the wire **34** by swedging or equivalent fixation technique. Next, any extension of the wire **34** beyond enlarged portion **38** is removed or cut off from the fastener assembly **20**.

When the fastener **20** is in its free state (i.e., with the wire **34** in its undeformed configuration and the coil **26** having substantially no axial compression forces applied to its ends), loops of the coil are generally spaced from one another and do not exert a significant opening force on the wire **34** (FIG. 5). In examples using a platinum coil, there is almost no force applied to the wire **34**. Although the force may be negligible, the platinum coil does not assist in the closing of the fastener. In using a more resilient coil, however, since the coil was initially formed in a straight configuration, there may be some amount of residual stress in the coil when it is placed in the substantially spiral configuration and thus some force may be applied to the wire **34** when the fastener is in its free state.

When the spring **26** is compressed (with the wire **34** in its deformed configuration as shown in FIG. 4), loops of the coil on the inner portion **46** of the spring are squeezed together with a tight pitch so that the loops are contiguous with one another while loops on the outer portion **48** of the spring are spaced from one another (FIG. 4). This is due to the compressed inner arc length of the spring **26** and the expanded outer arc length of the spring. The compression of the loops on the inner portion **46** of the spring **26** exerts a force on the inner side of the wire **34** which forces the wire to spread open (i.e., tends to straighten the wire from its closed configuration to its open configuration). The end of the spring **26** adjacent the enlarged portion **38** is held in a fixed position relative to the wire **34**. The opposite end of the spring **26** is free to move along the wire **34** and is held in place when the spring is in its compressed position by a locking device or release mechanism **28a**.

When the release mechanism **28a** is removed from the wire **34** and enlarged portion **36**, the spring or coil **26** releases stored energy and expands to abut against the enlarged portion **36** again, which also allows the wire **34** to resume its substantially spiral shaped configuration, thereby also conforming the coil **26** into the substantially spiral-shaped configuration. Because the coil was not originally formed in the substantially spiral-shaped configuration, its tendency, if unaffected by outside forces, would be to return to the straight configuration, or possibly to remain in its present configuration, as in the case of a thin, malleable, platinum coil. Thus, the coil **26**, at best, does not aid the wire **34** in returning the fastener **20** to its closed position or free state, and, at worst, actually hinders the wire **34** from returning to the closed position. This further translates to possibly reducing the static closing force of the fastener somewhat.

In an example according to the present invention, shown in FIG. 1A, a fastener **140** is formed such that the coil **146** assists the wire **154** in its return to the closed state. In this embodiment, the coil **146** forms an integral part of the fastener (i.e., fastening system) so as to assist in the closing thereof. In making the fastener **140**, the wire **154** may be first formed in the generally spiral shaped configuration shown in FIG. 2. The wire **154** is wound on a clip fixture, e.g. a tapered shaft (not shown), and is then heat treated, in a first heat cycle, in a convection oven set at a temperature ranging from about 450° C. to less than about 500° C. for a period of about one to twenty minutes, to set the desired shape (e.g., the shape

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shown in FIG. 2) of the bare clip **154**. In one example, the wire is heated in a first heat cycle at a temperature of about 475° C. for about six minutes. The first heat cycle does not fully remove the cold worked stresses in the wire **154**, since the first heat cycle is performed below 500° C. Of course, the wire **154** may be formed in various other configurations, some examples of which are described in application Ser. No. 09/090,305, the entire contents of which are hereby incorporated by reference thereto. Enlarged portion **156** is formed prior to the first heat cycle of the wire **154**, and may be formed by attaching a member to the end of wire **154** by welding, gluing or other suitable attachment means or may be formed integrally with the wire by deforming the end of the wire, such as by heat (melting).

Coil **146** is formed by first wrapping a wire of shape memory material, such as Nitinol around a cylindrical mandrel (not shown) and then heat setting the wire in a first heat cycle by placing it and the mandrel in a convection oven set at a temperature ranging from about 450° C. to less than about 500° C. for a period of about one to twenty minutes, to set it in an axially straight, configuration such as shown in FIG. 3A. In one example, the coil is heated in a first heat cycle at a temperature of about 475° C. for about six minutes. For an even stiffer configuration with correspondingly greater spring recoil, a pair of Nitinol wires (each preferably having about the same length and diameter as wire **146**) **146a, 146b** may be wound side-by-side around the cylindrical mandrel and then heat set in a first heat cycle by placing the pair and the mandrel in a convection oven and heat treating in a first heat cycle according to the parameters described above, to set it in an axially straight, double coil configuration **146'**, such as shown in FIG. 3B. Of course, other materials which exhibit a sufficient shape memory ability could be substituted for Nitinol, as would be apparent to one of ordinary skill in the art. Also, more than two adjacent wires (e.g., 3, 4 or more) may be wrapped and heat set in a similar procedure.

Next, the coil **146'** (or **146**, depending on whether a double or single coil (or more) is used) is axially slid over the wire clip **154**, such that the leading end of the coil **146'** abuts or lies adjacent to the enlarged portion **156**, whereupon it takes on the substantially spiral-shaped configuration of the wire **154**, as shown in FIG. 6. Once in position on the wire **154**, the assembly (wire **154** and coil **146, 146'**) is again heat treated in a second heat cycle, this time in a salt bath, to form an integrated system, wherein the shapes of both components are formed to one another so as to function in concert upon closing of the fastener. The salt bath may be sodium nitrate and potassium nitrate in a 50/50 mixture by weight percent for example. Alternatively, other molten mixtures could be used as would be apparent to those of ordinary skill in the art. The purpose of the salt bath is to provide a much more stable process, with more efficient and constant heat transfer to the entire assembly, thereby optimizing the strength of the fastener by removing any residual cold-worked stress in the materials to optimize the configuration of the fastener.

The salt bath is heated to a temperature of about 500-530° C. and the fastener is submerged therein for a period of about one to six minutes. In one example, the fastener may be submerged in a salt bath having a temperature of about 515° C. for about two minutes. The shape of the coil **146** after treatment in the salt bath cycle, is memory set into the shape of the clip **154**, as shown in FIG. 1A, for example, so that each component has a substantially spiral-shaped memory set. Of course, other shapes of the wire **154** could be made initially, as noted above, after which the coil **146** would be processed in the same way as described above, to take on a memory set provided by the shape of the wire **154**.

After heat setting as described above, the fastener is assembled with a locking mechanism, much in the same manner as described above with regard to previous embodiments. Although the enlarged portions have been described with spherical and cylindrical configurations, other configurations or configuration combinations can be used. For example, both enlarged portions may be spherical or both may be cylindrical, etc.

After heat setting the coil **146,146'** and wire **154** in the second heat cycle, a locking mechanism, such as **28a** for example, is locked in position over the enlarged portion **156**. Afterwards, an additional enlarged portion **158** is slid on the wire **154** and driven against the coil **146,146'** to compress the same and open the fastener (FIG. 7). While the fastener is in the open position, the enlarged portion **158** is then fixed to the wire **154** by swedging or equivalent fixation technique. Next, any extension of the wire **154** beyond enlarged portion **158** is removed or cut off from the fastener assembly **140**. Although enlarged portions **156** and **158** are shown with spherical and cylindrical configurations, other configurations or configuration combinations can be used. For example, both enlarged portions may be spherical or cylindrical, or portion **156** may be cylindrical and portion **158** spherical.

When the fastener **140** is in its free state (i.e., with the wire **154** in its undeformed configuration and the coil **146** having substantially no axial compression forces applied to its ends), loops of the coil are generally spaced from one another and do not exert a substantial force on the wire **154** (FIG. 1). This is because of the memory set that was fixed in the coil **146** during the preparation of the fastener **140** as described above. Because the memory of the coil **146** has been formed to take on essentially the same configuration as the memory set of the wire **154** when no external forces are applied to the fastener **140**, the coil **146** does not "fight against" the closure of the wire **154** as it moves toward its free state. As a further illustration, FIG. 8 shows that even if the coil **146** is removed from the clip **154**, it will still assume the general spiral-shaped configuration (or other configuration to which its memory was set while mounted on a wire **154**). Thus, the free state of the coil **146** cooperates with the free state of the wire **154**.

When the spring **146** is compressed (with the wire **146** in its deformed configuration as shown in FIG. 7), loops of the coil on the inner portion **146'** of the spring are squeezed together with a tight pitch so that the loops are contiguous with one another while loops on the outer portion **146"** of the spring are spaced from one another (FIG. 7). This is due to the compressed inner arc length of the spring **146** and the expanded outer arc length of the spring. The compression of the loops on the inner portion **146'** of the spring **146** exerts a force on the inner side of the wire **154** which forces the wire to spread open (i.e., tends to straighten the wire from its closed configuration to its open configuration). It should be understood, however, that a coil (not shown) having sufficient stiffness, for example, may be used where adjacent loops do not contact one another when the coil is compressed to force wire **154** into an open position. The end of the spring **146** adjacent the enlarged portion **158** is held in a fixed position relative to the wire **154**. The opposite end of the spring **146** is free to move along the wire **154** and is held in place when the spring is in its compressed position by a locking device or release mechanism **28a**.

When the release mechanism **28a** is removed from the wire **154/enlarged portion 156**, the spring or coil **146** releases stored energy and expands to again abut against the enlarged portion **156**. At the same time, both the coil **146** and the wire **154** move in concert to return to the "free" or closed configuration shown in FIG. 1. Thus, because of the memory set of

the coil **146**, as well as the wire **154**, coil **146** actually assists wire **154** in the closing of the fastener **140** upon removal of the release mechanism **28a**.

Referring to FIGS. 1 and 7, fastener **140** is shown in closed and open configurations. When wire **154** is in an undeformed or closed configuration, the fastener is closed (FIG. 1) for keeping or connecting tissue together. When wire **154** is in a deformed or open configuration, the fastener is open (FIG. 7) for insertion of the wire into tissue. As discussed above, wire **154** is in its closed configuration when in a relaxed state, and likewise, coil **146** is in a closed configuration when in a relaxed state. Wire **154** and coil **146** are preferably not deformed past their yield points in the open position. Accordingly, fastener **140** may have a U-shaped configuration in its open position to facilitate insertion of the wire through the tissue. However, other configurations may be used including, but not limited to C-shaped, V-shaped, J-shaped, and other similarly shaped configurations.

The helical wire **154** may have other cross-sectional shapes and be formed of different materials which exhibit shape memory characteristics. Coil **146** is preferably sized so that when in its free (uncompressed state) it extends the length of wire **154** with one end adjacent to enlarged portion **156** and the other end adjacent to enlarged portion **158**. It is to be understood that the coil may not extend the full length of the wire. For example, a flange or similar device may be provided on an intermediate portion of wire **154** to limit movement of the coil along the length of the wire.

In addition to the configuration shown in FIG. 5 and the alternative configurations taught in application Ser Nos. 09/090,305; 09/259,205; 09/089,884; and 09/260,623; all of which are incorporated herein in their entireties by reference thereto, a fastener according to the present invention can be formed in still other configurations. One or both ends of the fastener may extend in a substantially straight direction from the curved form of the wire **154**. The straight sections of extensions may extend for a length equal to about two to three times the outside diameter of the coil **146** (as compared to the diameter of the loop) or about 0.010 to 0.020 inches. These extensions may allow the release mechanisms (discussed in detail below) to operate more efficiently and also may simplify manufacture of the fastener.

The fastener may be embodied by a wire (a small clip), having a cross-sectional thickness of about 0.0035 inches, which, similar to the closed configuration of the prior art fastener shown in FIG. 5, forms an inner loop having a diameter D_1 of about 0.017 inches and an outer loop dimension D_2 (horizontally measured from inside of the loop) of about 0.021 inches. In the open configuration, the exemplary clip may form a U-shape with a depth of the U-shape being about 0.032 inch (0.8 mm).

Referring to FIGS. 1B and 1C, a fastener **140'** with two extensions and a stopper **142** is shown. The stopper preferably is slidably mounted onto the wire **154** in the vicinity of the transition from a curved wire portion, to the relatively straight extension. The stopper is placed between discrete springs **146"** and **146'''** and held in place thereby. Either or both of springs **146"** and **146'''** may be single or double coils (or more) as described above and may be set according to the procedures described with regard to coils **146** and **146'**.

The embodiment of FIGS. 1B and 1C is particularly advantageous for anastomosing a relatively thin-walled vessel to a relatively thick-walled vessel (e.g., the aorta or other large vessel), where an extension acts to prevent the relatively thin-walled vessel from sliding into the anastomosis site and out of the preferred position where it is to be fixed, as is illustrated in FIG. 1C.

For example, this fastener design may be embodied by a wire (wire **154**) having a cross-sectional thickness of about 0.0045 inches, which, in the closed configuration shown forms an inner loop having a diameter D_1 of about 0.060 inches and an outer loop dimension D_2 of about 0.065 inches. In the open configuration, the fastener forms a U-shape with a depth of the U-shape being about 0.07-0.09 inch (1.5 to 2 mm).

It is to be understood that the fasteners may have undeformed or deformed configurations different than those shown herein without departing from the scope of the invention. In addition, a locking clip (not shown) may also be attached to connect the ends of the fastener when the fastener is in its closed position to prevent possible opening of the fastener over time. The locking clip may also be integrally formed with one end of the fastener.

In the example shown in FIG. 9, the tissue connector assembly **10** generally comprises a tissue piercing or penetrating member **16**, a flexible member **18**, and a fastener or surgical clip **140**. A restraining device, generally indicated at **24** and comprising a spring (or coil) **146** and a locking device (or release mechanism or coupling member) generally indicated at **28**, is connected to the fastener **140** for holding the fastener in a deformed configuration as further described below.

Piercing or penetrating member **16**, which may be in the form of a needle (such as a 7-0 or 8-0 needle), has a sharp pointed tip **30** at its distal end for penetrating tissue. Member **16** may be bent as shown in FIG. 9, for example. The diameter of at least a portion of member or needle **16** is preferably greater than the diameter of flexible member **18** so that the flexible member can easily be pulled through an opening formed in the tissue by the needle. The distal end of member or needle **16** is preferably rigid to facilitate penetration of tissue. The remaining length of member or needle **16** may be rigid or flexible to facilitate movement of the needle through the tissue as further described below. The tip **30** of member or needle **16** may have various configurations and may, for example, be conical, tapered, or grounded to attain a three or four facet tip. Member or needle **16** may be made from stainless steel or any other suitable material, such as a polymeric material. It is to be understood that member or needle **16** may have a shape or radius of curvature other than the one shown, without departing from the scope of the invention. Member or needle **16** may also be integrally formed with the flexible member **18** (e.g., both needle and flexible member formed of the same material.)

Flexible member **18** may be in the form of a suture formed from conventional filament material, metal alloy such as Nitinol, polymeric material, or any other suitable material. The material may be non-stretchable or stretchable, solid or hollow, and have various cross-sectional diameters. The flexible member or suture may have a cross-sectional diameter of 0.003 inch, for example. The diameter and length of the suture will vary depending on the specific application. The suture may be attached to the needle **16** by crimping or swaging the piercing member or needle onto the suture, gluing the suture to the piercing member or needle, or any other suitable attachment method. Flexible member **18** may have cross-sectional shapes other than the one shown herein and may have other constructions as well.

Referring to FIGS. 10A and 10B, one release mechanism for coupling the fastener to the suture and needle is generally indicated with reference numeral **28a**. Locking device or release mechanism **28a** comprises a plurality of substantially rigid strands, preferably wires **106**, arranged substantially parallel to one another and circularly about a longitudinal axis

of the aligned strands, to form a tube-like configuration, as can be seen in the cross-sectional view of FIG. 10B. Alternatively, strands **106** may be cables or some other substantially rigid strand elements arranged in the same manner as the wires shown in FIG. 10B. Upon arrangement into the circular configuration, the hidden end portions **106a** of the strands are coupled to tapered section **2**, which is coupled to a piercing member or needle through a flexible member such as flexible member **18**.

Preferably, a rod **162** extends from tapered section **2** to facilitate fixation of the strands thereto. The coupling of the strands to tapered section **2** is preferably accomplished by gluing or soldering to rod **162**, although other equivalent or similar known joining techniques may be employed (e.g., welding, threadably attaching, etc). Similarly, rod **162** is preferably glued, soldered or threaded into the needle or transition element. In an alternate arrangement, the flexible member may extend through tapered section **2** and form a substitute structure for rod **162**. This may be preferred when the flexible member is a metal wire.

The end portions **106b** of the strands in the vicinity of the fastener strands include notches **109** which are formed into the strands to a depth equal to approximately half the diameter of the strand **106**. When the strands are arranged in the circular configuration described above, the notches **109** form a chamber **108** configured for receiving and holding enlarged portion **156**. Although enlarged portion **156** is shown as having a spherical shape, it may have other shapes including a barrel shape, or other shape that may be easily grasped and easily released.

The notches are preferably placed about 0.015" from the free ends of the strands, but this distance, of course, can be modified, depending upon the amount of compression of spring **146** that is desired when ball **156** is inserted into the chamber **108** and held by notches **109**.

After placement of ball **156** within chamber **108** formed by notches **109**, a shrink wrap layer, preferably a shrink tubing **110** may be provided over at least free end portions **106b** of wires or strands **106**, and the tubing heated to compress against strands **106** and hold them in place against ball **156**, preferably symmetrically against ball **156**. Together, tubing **110** and strands **106** effectively hold ball **156** captive within notches **109**. Alternatively, other plastic or elastic restraining members may be mounted around the distal portions of the wires or strands to aid in maintaining them in place, preferably symmetrically against ball **156**. Still further, strand members may be designed with an elastic spring force sufficient to maintain notches **109** in place with sufficient force to maintain the ball **156** captive therein under the tensile forces normally experienced during a suturing procedure. Although a seven strand embodiment is shown, it should be understood that fewer or more than seven strands may be used. The number of strands may vary depending on, for example, the size of the clip or the size of the strands. Typically, the number of strands may range from two to ten. In a coronary anastomosis, the number of strands preferably will range from five to seven although other numbers may be used.

In assembly, enlarged portion **156** of wire **154** is placed in chamber **108**. Tubing **110** is wrapped around at least a portion of the strands (as shown in the drawings) and heated to maintain enlarged portion **156** captive within the cavity formed by the strands. Compression coil or spring **146** is slid over wire **154** and enlarged portion **158** is slid over the wire **154** and slid against spring **146** to compress the coil against portions **106b** such that the fastener is in its open configuration. Enlarged portion **158** may then be swedged or otherwise fixed to wire **154** to maintain the fastener in its open configuration.

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Release mechanism **28a** is movable between a locked position and an unlocked position. In the locked position the ball **156** is held within notches **109** and consequently, coil **146** is held in its compressed position, thereby maintaining fastener wire **154** in its deformed or open position. In the unlocked position, ball **156** is released from the notches, thereby allowing the coil **146** to expand, and releasing the closing forces produced by both the wire **154** and the coil **146**, causing the fastener **140** to close. As noted above, the coil **146** remains integral with the wire **154** upon closing of the fastener **140**. The closing actions or forces provided by the wire **154** and coil **146** act in concert to provide an optimal closing force of the fastener upon the tissues, tissue and graft, etc. The coil **146** remains integral with the wire or clip **154** after closing of the fastener **140**, and both components cooperate to maintain the anastomosis.

Movement of the release mechanism to the open position is accomplished by applying a compressive force to the shrink tube **110** and bundle of strands **106**. Advantageously, the compressive force may be applied at any opposing locations around the circumference of the shrink tube as long as the implement applying the force is oriented at an angle to the strands, preferably substantially perpendicular thereto, to allow the implement to traverse the strands so as to deform the positions thereof when the force is applied. The strands or wires **106** get distorted from their circular configuration under the compression. This change in shape stretches the shrink tube **110** from a circular configuration to a somewhat elliptical configuration, and removes some of the notches **109** from contact with ball **156**, thereby permitting removal of ball **156** from within the chamber previously formed by notches **109** in the closed position.

The tissue connector assembly **10**, has many uses. It may be especially useful for minimally invasive surgical procedures including creating an anastomosis between a vascular graft **12** and an artery **14** (FIGS. 11A-11C). The anastomosis may be used to replace or bypass a diseased, occluded or injured artery. A coronary bypass graft procedure requires that a source of arterial blood flow be prepared for subsequent bypass connection to a diseased artery. An arterial graft may be used to provide a source of blood flow, or a free graft may be used and connected at the proximal end to a source of blood flow. Preferably, the source of blood flow is one of any number of existing arteries which may be dissected in preparation for the bypass graft procedure. In many instances it is preferred to use the left internal mammary artery (LIMA) or the right internal mammary artery (RIMA), for example. Other vessels which may be used include the saphenous vein, gastroepiploic artery in the abdomen, radial artery, and other arteries harvested from the patient's body as well as synthetic graft materials, such as DACRON® (polyester fibers) or GORETEX® (expanded polytetrafluoroethylene). If a free graft vessel is used, the upstream end of the dissected vessel, which is the arterial blood source, will be secured to the aorta to provide the desired bypass blood flow, as is well known by those skilled in the art. The downstream end of the graft vessel is trimmed for attachment to an artery, such as the left anterior descending coronary (LAD). It is to be understood that the anastomosis may be formed in other vessels or tissue.

The patient is first prepped for standard cardiac surgery. After exposure and control of the artery **14**, occlusion and reperfusion may be performed as required. An arteriotomy is performed on artery **14** to provide an opening **120** for receiving a graft vessel (FIG. 11A). After the snared graft vessel **12** has been prepared and made to the appropriate length as would be conventional in the art, a tissue connector assembly **10** is attached to the free end of the graft vessel along an edge

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margin of the vessel. In order to attach the connector assembly **10**, the surgeon grasps the needle **16** with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts the needle **16** into the tissue of the graft vessel **12** in a direction from the exterior of the vessel to the interior of the vessel. The surgeon then releases the needle **16** and grasps a forward end of the needle which is now located inside the graft vessel **12** and pulls the needle and a portion of the suture **18** through the vessel. The needle **16** is passed through opening **120** formed in the sidewall of the artery **14** and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps the needle **16** located outside the artery **14** and pulls the needle and a portion of the suture **18** through the arterial wall. A second tissue connector assembly **10** may be inserted at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

Once the tissue connector assemblies **10** are inserted, the graft vessel **12** is positioned above and aligned with the opening **120** in the sidewall of the artery **14** (FIG. 1A). A section of each suture **18** is located between the graft vessel **12** and artery **14**. The fasteners **140** and needles **16** are pulled generally away from the artery **14** to reduce the length of the suture **18** (eliminate slack of the suture) between the vessel **12** and artery and "parachute" the vessel onto the artery (FIG. 11B). The needles **16** are then pulled away from the artery **14** until each fastener **140** is positioned within the graft vessel **12** and artery with one end of each fastener **140** extending from the vessel and the opposite end of each fastener extending from the artery.

A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device **28** to release the locking device from the fastener **140**. Upon removal of the locking device **28**, the coil **146** moves to its free uncompressed state which allows both the wire **154** and coil **146** to return to their memory configurations which define the closed position (FIG. 11C). As the wires **140** move to their closed positions the adjacent tissues of the graft vessel **12** and artery **14** which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery. The graft and arteriotomy edges may be abutted or everted as is known in the art. It should be noted that as the locking device **28** is squeezed two steps are accomplished. The fastener **140** is released from the locking device **28**, thus allowing the coil **146** to uncompress and the wire **154** and coil **146** to close, and the needle **16** is released from the fastener. Thus, in this embodiment, the locking device **28** provides for simultaneous actuating closure of the fastener **140** and release of the needle **16** from the fastener.

In this example, two tissue connector assemblies **10** are used to make connections at generally opposite sides of the graft vessel. Additional tissue connector assemblies **10** may be used to make connections between those. The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for example. The procedure may also be performed endoscopically.

As an alternative to inserting tissue connector assemblies **10** at "heel and toe" locations described above, a number of tissue connectors **10** may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis. In a further alternative, double needle assemblies **11** (FIG. 12 described below) are used. Each needle of a double needle assembly **11** is passed from inside

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to outside of the respective graft and artery. The first assembly is placed at the "heel" (6 O'clock) position, the tissue brought together in the clip and the clip closed. Another double needle assembly is then placed at the 5 O'clock position and closed, 7 O'clock position and closed, 12 O'clock position and closed, 1 O'clock position and closed, 11 O'clock position and closed. Three single needle assemblies **10** are then evenly spaced between the 6 and 12 O'clock positions (placed laterally) and the tissue placed therein. These fasteners are then closed. Three more single needle assemblies **10** are placed on the other lateral side of the anastomosis in the same manner as the first lateral fasteners.

Referring to FIG. **12**, the multiple piercing member construction facilitates threading ends of the assembly from inner to outer wall(s) of material, such as tissue, which may eliminate or minimize the possibility of dislodging material, such as plaque, from the inner wall of calcified arteries, for example, as will become more apparent from the description provided below. In a preferred embodiment, two piercing members, each of which may comprise a needle, are releasably coupled to a fastener. The coupling between the flexible member (and, thus, the piercing member) and the fastener may be constructed to actuate closure of the fastener upon release of the flexible member (or piercing member). For example, the coupling may hold a compression spring (which is positioned around a fastener) in a compressed state to brace the fastener open and releasably lock or secure the fastener to the flexible member (or piercing member).

As shown in FIG. **12**, a tissue connector assembly **11**, which generally comprises tissue piercing or penetrating members **16** and **17**, flexible members **18** and **19**, and a fastener **140** (e.g., a surgical clip) is shown. A restraining device, generally indicated at **24** and comprising a spring (or coil) **26** and a locking device (or coupling member) generally indicated at **28**, is connected to fastener **140** for holding the fastener in a deformed or open configuration as described previously. That is, the spring or coil is adapted to be integrated with the wire or clip, to act in concert therewith, for closing the fastener with and optimal closing force and action. Penetrating or piercing member **17** may be made in accordance with the description provided above in connection with penetrating member **16**, and, thus may, for example, be in the form of a needle (such as a 7-0 or 8-0 needle) having a sharp pointed tip **31** at its distal end for penetrating tissue. Members **16** and **17** may be the same or differ from one another. Flexible members **18** and **19** also may have the same construction.

Referring to FIG. **13A**, release mechanism **28a** also may be used to releasably couple the other end of the fastener to another flexible member such as flexible member **19**, which in turn, is coupled to a needle such as needle **17** as shown in FIG. **12**. In this arrangement, a member or stopper **115**, which may be annular, is secured to the other end of the fastener or wire **154** to prevent enlarged portion **156** or **158** (since wire **154** may have substantially symmetrical ends when employing double penetrating members) from passing through the compression spring upon release from release mechanism **28a**.

FIGS. **13B** and **13C** illustrate a synchronized fastener release system. One release mechanism may correspond to mechanism **28a**. At the other end of the fastener or wire **154**, a release mechanism which responds to the compressive state of coil **146** and releases the fastener or wire **154** upon release of compressive forces on the coil is shown and generally designated with reference numeral **29a**. Referring to FIGS. **13B** and **13C**, release mechanism **29a** comprises two members **121** each having a recess **122** formed therein and arranged to form chamber **124** when members **121** are

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aligned as shown in FIG. **13B**. Recesses **122** are configured to retain enlarged portion **156** or **158**, which is shown with a cylindrical configuration, but may have a spherical or other suitable shape for operatively associating with a suitably configured chamber. Further, members **121** may have semicircular transverse cross sections or some other combination of transverse shapes that can collectively provide the desired chamber to retain enlarged portion **156** or **158**. The number of members **121** also may vary as would be apparent to one of ordinary skill.

Release mechanism members **121** have tapered ends **126**, which are configured for positioning between coil **146** and fastener wire **154** as shown in FIG. **13B**. When tapered ends **126** are so positioned and coil **146** is in a compressed state, coil **146** holds tapered ends **126**, which are normally biased away from each other, sufficiently together to retain enlarged portion **156** or **158** within chamber **124**. When release mechanism **28a** is actuated (e.g., radially compressed) to release enlarged portion **156** or **158** of fastener wire **154**, coil **146** assumes its relaxed state, thereby releasing tapered ends **126** of release mechanism **29a** from the coil and allowing the tapered ends to radially expand and release enlarged portion **156** or **158** of fastener wire **154**. Accordingly, both needles and flexible members may be decoupled from the fastener when release mechanism **28a** is actuated.

FIGS. **14A-14C** show another synchronized fastener system which is similar to the system shown in FIGS. **13A-13C**. Release mechanism **28c** may be of the type described above with regard to reference numeral **28a** or may be a variety of other mechanisms including those described in copending, commonly assigned application Ser. Nos. 09/090,305, filed Jun. 3, 1998; 09/089,884, filed Jun. 3, 1998; 09/259,705, filed Mar. 1, 1999; and 09/260,623, filed Mar. 1, 1999; all of which are incorporated herein by reference thereto, in their entireties. Release mechanism **29b** and the cooperating portion of the fastener or wire **154** are also varied from release mechanism **29a**. In this embodiment, an annular member or stopper **115**, which may be annular, is slidably coupled to fastener wire **154**. Member **115** is configured to resist passage of coil **146** thereover. Accordingly, member **115** may have an outer diameter slightly greater than at least the portion of the coil adjacent thereto. A tapered or frustoconical member **3'** is secured to an end of fastener wire **154**, which need not include an enlarged portion. Member **3'** is the same as member **3** with the exception that member **3'** has a channel **134** for receiving flexible member or suture **19**. Channel **134** extends radially outward from bore **132**, which is formed through member **3'**, for receiving the fastener or wire **154** (FIG. **14C**).

Flexible member **19** is threaded through channel **134** and between tapered member **3'** and annular member **115**. When coil **146** is in a compressed state as shown in FIG. **14A**, the coil urges member **115** toward tapered member **3'** and compresses flexible member **19** therebetween. In this manner, flexible member **19** is secured to the fastener or wire **154**. When release mechanism **28c** is actuated (e.g., radially compressed) to release enlarged portion **156** of the fastener or wire **154**, coil **146** assumes its relaxed state so that annular member **115** may slide away from tapered member **3'** and release flexible member **19**. Accordingly, both needles and flexible members may be removed from the fastener when release mechanism **28c** is actuated. Although a metal flexible member may be used, a polymeric flexible member may be preferred.

Because of its potentially very small size and its tendency to wrap itself snugly around tissue, the fastener may not leave much to grab onto for its removal if desired. In addition, there may be no free ends to grab, which may make it difficult to

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remove without damaging the tissue around which it is wrapped. The following is a detailed description of removal apparatus and methods according to the present invention.

Referring to FIGS. 15A-15C, one embodiment of a removal apparatus 200 is shown. In the embodiment, the apparatus generally comprises a grabber member 204 having a hook 210 and slidably mounted within sleeve 212. Sleeve 212 may have a blunt distal end so that it may restrain tissue movement as the fastener is drawn therefrom. Sleeve 212 may be mounted within housing 206, which includes a slot 214 through which flange 216 of sliding button 208 is disposed. One end of the flange 216 is secured to the grabber member so that the grabber member can be withdrawn and extended from the sleeve as shown in FIGS. 15A and 15B.

The hook may be formed at an angle of about 50-70 degrees (α) and has a width ("z") and depth ("y") slightly larger than the diameter of wire 154 and coil 146 (or 146', 146", 146''') (e.g., about 0.001 inch greater than the diameter of the wire and coil). "z" and "y" thus may be essentially the same and may be in the range of about 0.005-0.020 inch. This configuration has been found to enhance the grabber member's ability to grab the fastener and pull it out of the tissue or material in which it is placed.

Referring to FIGS. 16A-16D, fastener removal is diagrammatically shown. After the fastener wire is placed in the slot of the hook, it is pulled inside the tubular sleeve 212. As the fastener enters the sleeve, it is bent in half and the coils surrounding the clip wire are compressed down towards the ends of the clip. This bending of the clip wire, combined with the compression of the coil causes the clip to open up enough to be pulled out of the tissue without damaging it and up into the tube or sleeve 212. As shown in FIG. 15C, which is a top view of the grabber member, a portion of the grabber member adjacent the hook, has a reduced thickness to provide sufficient space for the fastener to be drawn within the sleeve, while straightening the wire and coil as it is pulled therein. The space "s" on each side of the member generally corresponds to the diameter of the wire and coil and may range, for example, from about 0.004 to 0.010 inch.

The hooked grabbing member can be retracted into the tube as described above. Alternatively, the sleeve 212 can be slidably mounted in housing 206 and attached to flange 216 of button 208, with the hooked grabbing member being fixed to the housing 206. In this variation, one can slide button 208 along slot 214 to slide sleeve 212 over the grabbing member to open or straighten the fastener.

Although a hooked grabbing mechanism is shown, it should be understood that other grabbing mechanisms can be used. Examples of other mechanisms include, but are not limited to, alligator-type jaws or a lasso-like wire loop as shown in FIGS. 17A-B and 18A-B, respectively. In the jaws variation, the jaw portion has a reduced width to allow entry of the fastener as in the hooked grabber as shown in FIG. 15C. In the loop embodiment, the sleeve lumen is sufficiently small to generally straighten the fastener 140.

Another grabber displacement mechanism also is shown in FIGS. 17A and 17B for use with the present invention. According to this embodiment, a cam system is used to actuate movement of the grabber member. Although not shown, it should be understood that the cam system can be arranged to reciprocate the sleeve instead of the grabber member. One or more buttons 208' are pivotally mounted to housing 206 to engage cam member 218, which may be in the form of a frustoconical member surrounding a portion of the grabber member, such as jaws type grabber member 220. A restraint such as coil spring 222 is placed between the cam member and housing annular flange 224 to bias the grabber into the

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sleeve as shown in FIG. 17A. As the buttons 208' are squeezed, the buttons engage camming surfaces 226 and force the grabber member out from sleeve 212 as shown in FIG. 17B.

Further can actuated grabber displacement mechanisms are shown in FIGS. 17C-D. These cam systems also are used to actuate movement of the grabber member. Actuator or cam member 208" is pivotally mounted to housing 206 at pin "p". The actuator comprises a lever arm and camming projection or interface 209 which extends from the lever arm to engage camming surface 226' of cam follower member 218'. Cam follower 218' preferably is secured to one end of the grabber member, which may be hook grabber member 204. A restraint, such as coil spring 223, is placed between the cam follower and sleeve 212 to bias the grabber into the sleeve as shown in FIG. 17C. As the actuator 208" is squeezed, cam projection 209 moves along camming surface 226' and imparts translational motion to the cam follower, which in turn, forces the grabber member out from sleeve 212 as shown in FIG. 17D.

Although not shown, it should be understood that any of the cam systems shown in FIGS. 17A-D can be arranged to reciprocate the sleeve instead of the grabber member.

Referring to FIGS. 18A and 18B, another actuating mechanism is shown in combination with a loop grabber. Instead of a camming surface, a simple linkage mechanism can provide the downward force when the buttons are squeezed. These opposing buttons may be hinged to the handle, 180 degrees apart. The buttons may comprise flaps 208''' extending from the housing and pivotally movable relative thereto. As in the illustrated embodiment, a circumferential groove 228 can be formed in the housing at the juncture where the flaps extend to enhance the pivoting capability of the flaps. As the flaps are compressed with the thumb and forefinger, they axially drive piston 228 through arms 230. Each arm is pivotally coupled to a flap and the piston as shown in the drawings. The piston is biased against such axial movement through coil spring 222, which is mounted between the piston and annular flange 224 of the housing. The piston is secured to the elongated grabber member 232 (which has loop 234 extend therefrom) so that the grabber member travels or reciprocates with the piston. The number of buttons may vary. For example, a single button actuator design can be used. It also should be understood that any of the actuating mechanisms and grabber mechanisms described above may be combined.

Referring to FIGS. 19A-19B, one embodiment is shown comprising a generally a two-part design that when assembled, resembles a pair of surgical tweezers or forceps. This embodiment is generally designated with reference numeral 300. There are two legs to the tweezers. The distal tip of each leg tapers down to less than about 0.010 inch thickness ("t", see FIG. 19C) at which point there is approximately a 90 degree bend inward, toward the other leg of the tweezers. This bent portion extends inward some distance (which may be about 0.1 inch) and may be about 0.035" in height. There is a slot cut through this bent-in portion that is the shape of a "V" or a "tapered U" and generally designated with reference numeral 302. The deepest part of the slot S_d is equal to or slightly larger than the diameter of the fastener wire 154. The other end of the slot is greater than the combined diameter of the wire 154 and coil 146 (146', 146", 146''') of the fastener. As the fastener moves in toward the closed end of the slot, the beveled portions wedge between coil turns and compresses the coil. The beveled portions each comprise a chamfer which extends all around slot 302. This forms something resembling a two-tined fork. One side of this thin profile member is completely flat, while the other side is chamfered around the

“V” profile (See FIG. 19C where β is about 55-65 degrees and may vary depending on the amount of taper to reach dimension “t”). The bevel is generally designated with numeral **304** (FIG. 19B). The flat sides of the member on each leg face each other, while the chamfered surfaces face outward away from each other. When the tweezers legs are squeezed together, the two flat, profiled, protruding members cross each other, with little or no space between their respective flat surfaces, somewhat resembling the shearing action of two scissors blades.

Referring to FIGS. 20A-20D, an example of fastener removal is shown. The surgeon simply brings one of the protruding members (forked parts) in at a right angle to the clip, and catches a portion of the clip in the “V” profile (between the tines of the fork). Once an arm of the clip is secured in the bottom of the “V”, the tweezers legs are squeezed together. As the two protruding members are brought into proximity (one with the clip in it), the clip becomes engaged in the “V” groove of the second member. At this point the clip is resisting (trapped) between the bottoms of the two “V” grooves. As the tweezers are squeezed further, the edges of the two “V” grooves are forced between the coils of the clip and, thus, come into contact with the clip wire itself. As the tweezers are squeezed further, two things occur: (1) the coils surrounding the clip wire are pushed to the ends (compressed), which inherently causes the clip to begin to straighten, and (2) the wire begins to bend. The combination of these two things (as in each grabber member apparatus described above) causes the clip to open slightly and loosen its grip on the tissue. This allows the clip to be extracted from the tissue.

Other tip configurations also can be used with this tweezers-style removal tool such as the variations shown in FIGS. 21 and 22. Most notably, one leg of the tweezers can have a double edge head at the end of it (FIG. 21). In other words, there are two protruding members, side-by-side at the tip. These two protruding members have enough space between them to allow the opposing protruding member on the other leg to slide between them. This configuration provides a more desirable bend in the clip, thus allowing easier removal. In FIG. 22, the beveled ends are turned about 90 degrees as compared to those in FIG. 19A.

Apparatus 200, with the “Hook and Slide” design, lends itself to standard conventional manufacturing techniques. The hook itself can be made from drawn wire (stainless steel or Nitinol) which has been machined at the tip to form the hook. Wire EDM or laser cutting could also be used to form this hook at the end of the wire. The handle and finger slider (or squeeze buttons) are best injection molded from any number of plastic resins, most likely ABS. The handle halves could then be easily sonic welded together. It is conceivable that these parts could be machined from metal or some other material, although this would be a much costlier option. The outer tube which slides over the hook can be extruded or drawn metal or plastic.

The “Shearing Tweezers” design has only two parts, both of which are machined from stainless steel or titanium blanks. The two machined pieces are welded together up near the top of the handle area.

In use, the instrument apparatus 200 is held by the surgeon in similar fashion to a pencil or surgical instrument, such as forceps or a probe. The hook is guided down to the clip and hooked around any part of the clip, preferably at a right angle to the clip. Once the hook is secured on the clip, the hook (with clip) is retracted into the outer tube of the device using the finger slider or squeeze buttons. If it is the wire loop or lasso, the loop must go over one of the free ends of the clip. The loop is then slid up onto the main part of the clip and then

retracted (with the clip) into the outer tube using the finger slider or squeeze buttons. At this point the clip is out of the tissue and completely contained within the outer tube. It can be retrieved by reversing the action of the finger slider or squeeze buttons to push it out of the tube.

The “Shearing Tweezers” are also simple to operate. The shearing tweezers are held just as any other surgical tweezers or forceps would be held. The surgeon guides the distal tip with the protruding member down to the clip and again, preferably at a right angle, slides the protruding member onto the clip. This is done so that the clip is resting in the bottom of the “V” groove, with one tine of the fork under the clip (between clip and tissue) and the other tine over the clip. Once in this position, the legs of the tweezers are squeezed closed. It sometimes requires multiple squeezes to be able to fully extract the clip. The tweezers design is well suited for reuse and sterilization, as it is made of only two parts, which are welded together to form one. A more comprehensive description of removal tools and procedures can be had by referring to our copending, commonly assigned application (Ser. No. 09/540,638 filed on even date herewith, titled “Surgical Clip Removal Apparatus”, which is hereby incorporated herein in its entirety, by reference thereto.

All references cited herein are incorporated by reference in their entirety.

While the above is a complete description of the preferred embodiments of the present invention, various alternatives, modifications and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined by the following claims.

The invention claimed is:

1. A method of making a surgical fastener, comprising: forming a clip element, formed of a shape memory material, into a predetermined closed configuration; positioning a coil over at least a portion of extension of said clip element; setting said clip element and said coil into said predetermined closed configuration to form a fastener comprising said clip element and said coil wherein each has a memory configuration which is said predetermined closed configuration.
2. The method of claim 1, further comprising: after said forming said clip element, setting said clip element by heating said clip element at a predetermined temperature for a predetermined time.
3. The method of claim 2, wherein said heating comprises heating at a temperature ranging from about 450° C. to less than about 500° C., and said predetermined time comprises a range from about one to twenty minutes.
4. The method of claim 3, wherein said heating comprises heating at about 475° C. and said predetermined time comprises about six minutes.
5. The method of claim 1, wherein said setting said clip element and said coil comprises heating said clip element and said coil in a salt bath at a predetermined temperature for a predetermined time.
6. The method of claim 5, wherein said heating comprises heating at about 500° C.-530° C. and said predetermined time comprises about one to six minutes.
7. The method of claim wherein said heating comprises heating at about 15° C. and said predetermined time comprises about two minutes.
8. The method of claim 1, further comprising: integrally attaching said coil to said clip element to form said fastener.

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9. The method of claim 1, further comprising:
 prior to said positioning said coil over said clip element,
 forming said coil in a straight axial configuration by
 winding said coil around a mandrel; and
 setting said coil in said straight axial configuration by
 heating said coil and said mandrel at a predetermined
 temperature for a predetermined time.

10. The method of claim 9, wherein said heating comprises
 heating at a temperature ranging from about 450° C. to less
 than about 500° C., and said predetermined time comprises a
 range from about one to twenty minutes.

11. The method of claim 10, wherein said heating com-
 prises heating at about 475° C. and said predetermined time
 comprises about six minutes.

12. The method of claim 9, wherein said coil comprises a
 double coil formed by wrapping two wires side by side
 around said mandrel.

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13. The method of claim 12, comprising using Nitinol
 wires to form said double coil.

14. The method of claim 9, wherein said coil is formed by
 wrapping more than two wires side by side around said man-
 drel.

15. The method of claim 1, wherein said step of setting said
 clip element and said coil comprises setting said clip element
 and said coil at the same time.

16. The method of claim 1, wherein said step of setting said
 clip element and said coil comprises setting said clip element
 prior to setting said coil.

17. The method of claim 16, wherein said step of setting
 said coil also comprises secondarily setting said clip element
 along with said coil.

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